Recruitment Strategy Success and Challenges in WISDOM 1.0: A Nationwide Risk-Based Breast Cancer Screening Trial

A. S. Fiscalini[1], T. Glatt[2], S. Goodman[1], C. Kaplan[1], A. Z. LaCroix[3], L. van 't Veer[1], M. Scheuner[4], P. Sales[5], A. Petruse[6], A. Naeim[6], A. Kaster[7], J. Wernisch[7] O. I. Olopade[8], B.Gonzales[8], H. L. Park[9], A. D. Borowsky[10], S. A. Raouf[10], J. Atamer[1], K. Leggat-Barr[2], J. Esserman[11], I. Cabaleiro[11], R. Lancaster[12], L. Anderson[12], D. Heditsian[1], S. Brain[1], V. Lee[1], D.Moorehead[13], B. A. Parker[3], A. Torres[1], L. Sabacan[1], L. Johansen[6], X. Calderon[6], A. Rocha[6], A. Verma[8], J. Cover[5], T. Miller[5], M. Che[1], N. Kim[14], T. Lewis[1], S. Kapoor[1], R. Soonavala[6], D.Goodman-Gruen[9], S. D. Stewart[10], R. A. Hiatt[1], N. Wenger[6], H. Anton-Culver[9], I. A. Soto[1], M. Eklund[15], K. F. Rhoads[1], L. J. Esserman[1]

[1]UCSF, [2]Tufts University, [3]UCSD, [4] San Francisco VA Health Care System, [5]N. California Institute for Research and Education, [6]UCLA, [7]Sanford Health, [8]University of Chicago, [9]UC Irvine,[10]UC Davis, [11]Diagnostic Center of Miami, [12]University of Alabama at Birmingham, [13]Women's Cancer Resource Center, Berkeley, CA, [14]Georgetown University, [15]Karolinska Institutet, Sweden

Abstract

The Women Informed to Screen Depending on Measures of risk (WISDOM) Study 1.0 (2016-2023; NCT02620852) tested a novel, risk-based approach to breast cancer screening compared to annual mammography. As a large-scale screening trial, WISDOM aimed to enroll individuals who reflect the heterogeneity of the U.S. population. We evaluated the recruitment strategies employed and their efficacy in building a geographically and racially diverse cohort of U.S. women.

Introduction

WISDOM 1.0 pragmatic trial: nationwide, web-based, preference-tolerant, comparing traditional annual screening to personalized risk-based breast screening.
Recruitment goal: 60,000
Eligibility criteria: ages 40-74, no history of invasive breast cancer or DCIS, reside in the US, identify as female.
Enrollment: adapted strategies to ensure a participant cohort representative of the US population



Figure 1. WISDOM's virtual enrollment components include online registration, consent and questionnaires; at-home saliva genetic testing kit

Methods and Materials

We analyzed enrollment and recruitment data, including participant responses to the 'How You Heard' (HYH) survey question at enrollment. Recruitment channels were grouped into categories and analyses were stratified by recruitment site and self-reported race/ethnicity. We evaluated the volume and proportion of participants recruited through each strategy, trends in outreach effectiveness over time, and differences by geography and participant demographics.

Results

Initial recruitment was limited to the Athena Breast Health Network within the University of California system (2016 - 2017) but expanded nationwide through external collaborations using virtual enrollment (Fig 3).

- Recruitment between 8/2016 -2/2023:
  - 70,575 women registered
  - 55,284 consented
  - 46,289 enrolled participants
- Provider/Medical Center yielded the highest enrollment across all time (Fig 2).
- VA outreach boosted enrollment by 25% and increased diversity
- Cohort diversity improved over time (Table 1) through: VA involvement, addition of new recruitment sites, involvement of community leadership advisors, and nationwide collaborations
- Strategy success varied by racial/ethnic background: VA contributed 26% of Black/AA and 10% Hispanic enrollment; Family/friend referrals accounted for over 7% of NH/PI but less than 4% for Black/AA, and 1.5% for AI/AN.

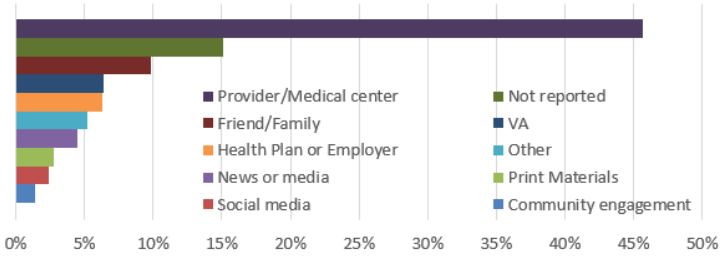


Figure 2. Recruitment volume by strategy

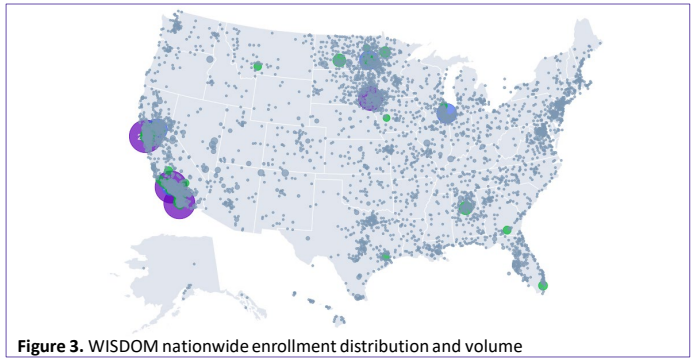


Figure 3. WISDOM nationwide enrollment distribution and volume

	White, NH	Black/ AA	NH/PI/AI /AN, NH	Asian, NH	2+ races NH	Hispanic/ Latino	Unknown/ 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%

Table 1. Improvements in racial/ethnic diversity over recruitment time period

Discussion

- WISDOM 1.0 demonstrated the **feasibility of recruiting a large, nationwide** screening cohort using multi-modal, decentralized outreach.
- **Physician emails and MyChart** were the most effective strategy, leveraging pre-existing patient trust and communication channels.
- The **VA collaboration** was both scalable and demographically impactful while friend/family referrals provided downstream enrollment benefits.

Conclusions and Future Directions

- WISDOM 2.0 launched in June 2023 refining high-yield, low-barrier strategies from 1.0, amplifying trusted voices, and integrating culturally responsive outreach to build a more representative national cohort.
- This pragmatic trial can inform future large scale studies aiming for diverse enrollment.
- WISDOM 1.0 outcomes (available in late 2025) will inform risk-based breast cancer screening and prevention and will require multi-level education and awareness efforts that use WISDOM's comprehensive outreach campaigns.

Advocates Perspective

Despite the unprecedented popularity of social media platforms, when it comes to health, trust is still the most important factor for patients.

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Contact
Allison Fiscalini, MPH
UCSF
Email: Allison.stoverfiscalini@ucsf.edu
Website: www.thewisdomstudy.org
Phone: 855-729-2844

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