Barriers to Enrollment in NRG-BR009 in West Virginia: Patient Treatment Preference as a Key Challenge in a Prospective Randomized Trial of Premenopausal Women with Intermediate Oncotype Scores

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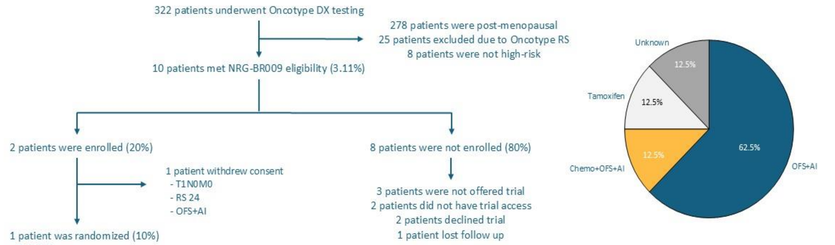
Introduction

- NRG-BR009 is a phase III randomized trial to determine whether chemotherapy can be safely omitted in premenopausal women with early-stage, estrogen receptor (ER)–positive, HER2-negative breast cancer and an intermediate Oncotype DX Recurrence Score® (16–25)
- The trial compares standard chemotherapy plus endocrine therapy to ovarian function suppression (OFS) plus endocrine therapy alone
- Despite the clinical promise of de-escalation, national accrual has been limited
- This study explores enrollment barriers within the West Virginia University Cancer Institute (WVUCI), a rural-academic network spanning both university and satellite cancer centers

Methods

- A real-time Epic-based dashboard was developed to track all patients for whom Oncotype DX testing was ordered from 5/22/2024 to 6/30/2025
- Structured interviews with clinical research teams and treating physicians were conducted to assess reasons for enrollment or non-enrollment, focusing on patient decision-making, provider communication, and operational barriers

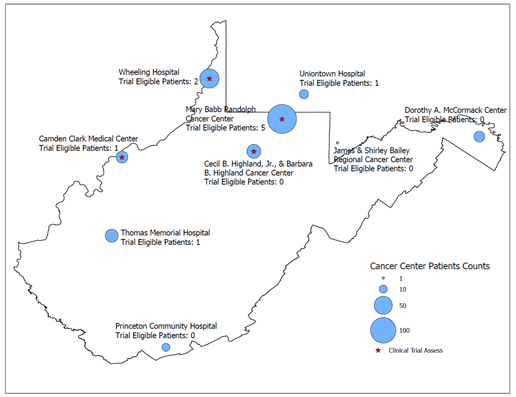
Patient Flow and Reasons for Non-Enrollment in NRG-BR009 Among Eligible Patients at the West Virginia University Cancer Institute



Barriers cited: Low trial eligibility, physician recommendation patterns, and strong patient preferences.
Common reasons for declining: Concerns about chemotherapy-related side effects and the perception of limited chemotherapy benefit.

Between May 1, 2024, and June 30, 2025, 322 patients underwent Oncotype DX testing. Ten patients (3.11%) met NRG-BR009 eligibility criteria. Two patients (20%) enrolled in the trial, of whom one withdrew consent due to poor wound healing. Eight patients (80%) were not enrolled, most commonly because the trial was not offered despite eligibility (n=3) or trial access was not available at the treating site (n=2). Additional reasons for non-enrollment included patient refusal (n=2) and loss to follow-up (n=1). The pie chart shows the adjuvant therapy choices among the 8 non-enrolled patients: ovarian function suppression plus aromatase inhibitor (OFS+AI) in 5/8 (62.5%), tamoxifen in 1/8 (12.5%), chemotherapy plus OFS+AI in 1/8 (12.5%), and unknown regimen in 1/8 (12.5%). Abbreviations: OFS, ovarian function suppression; AI, aromatase inhibitor; RS, Recurrence Score

Demographics



Patient Characteristics	Eligible	Ineligible
Age		
<50	6	33
50-60	4	59
>60	0	220
Gender		
Female	10	303
Male	0	9
Menopause Status		
Pre/perimenopause	10	45
Postmenopause	0	267
Oncotype Score		
<16	4	161
16-25	6	102
>25	0	50
Nodal status (N)		
Pos	4	47
Neg	6	265
Clinical Trial Access		
Yes	7	242
No	3	71
Chemotherapy		
Yes	1	44
No	9	268
Radiation Therapy		
Yes	6	197
No	4	115
Location		
MBRCC	4	128
Community	6	184

The left panel maps participating cancer centers, with blue circles sized by the number of trial-eligible patients identified between May 2024 and June 2025; red stars denote sites actively assessing trial eligibility. The right panel summarizes demographic and clinicopathologic characteristics of eligible and ineligible patients.

Results

- Physicians consistently cited both the limited number of eligible patients and strong pre-existing patient treatment preferences as key barriers to enrollment
- Many premenopausal patients expressed a preference for chemotherapy prior to surgery but later shifted toward OFS plus endocrine therapy after receiving an intermediate Recurrence Score postoperatively
- In most cases, patients had already made a treatment decision by the time of trial discussion and expressed reluctance to accept randomization
- Preferences were primarily driven by concerns regarding side effects, fertility preservation, and perceptions of limited absolute benefit from chemotherapy

Conclusions

- In a rural-academic cancer network, enrollment in NRG-BR009 was limited by both a small pool of eligible patients and pre-existing treatment preferences
- Despite timely trial discussions and centralized eligibility tracking, most patients declined participation due to discomfort with randomization and a preference for personalized treatment decisions
- These findings highlight the need for earlier engagement in shared decision-making, tailored decision-support tools, and strategies to maintain equipoise when offering clinical trials in preference-sensitive populations

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