World Stroke Organization

17TH WORLD STROKE CONGRESS

2025 OCTOBER 22—24 BARCELONA, SPAIN

ONE WORLD VOICE FOR STROKE

Factors Influencing Participation in the OCEANIC-STROKE Study (FIT Sub-study): Enhancing Equity in Global Stroke Trials

G. Sampaio, M. Sharma, C. Carcel, M. Knoflach, J. Oliveira-Filho, J. Gorman, H. Christensen, F.K. Hoo, E. Sandset, M. Arnold, D. Cross, S. Kasner, J. Saver, A. Wang, R. Rashed, A. Shoamanesh, E. Muehlhofer, R. Joundi

worldstrokecongress.org

Faculty Disclosure
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World Stroke Organization
17TH WORLD STROKE CONGRESS
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	No, nothing to disclose
X	Yes, please specify:

Company Name	*Honoraria/ Expenses*	*Consulting/ Advisory Board*	*Funded Research*	*Royalties/ Patent*	*Stock Options*	*Ownership/ Equity Position*	*Employee*	*Other (please specify)*
Boehringer Ingelheim	x	x	x					
Brazilian Ministry of Health			x				x	
Bayer	x	x	x					
National Institutes of Health (NIH)			x					

Diversity in clinical stroke trials

World Stroke Organization
17TH WORLD STROKE CONGRESS
2025 OCTOBER 22—24 BARCELONA, SPAIN

ORIGINAL RESEARCH

Disparities in Race and Ethnicity Reporting and Representation for Clinical Trials in Stroke: 2010 to 2020

Hely D. Nanavati, MPH, MBBS ; Mudasir Andrabi, PhD ; Yurany A. Arevalo, MD ; Evan Liu, BS ; Jeffrey Shen, MD ; Chen Lin, MD

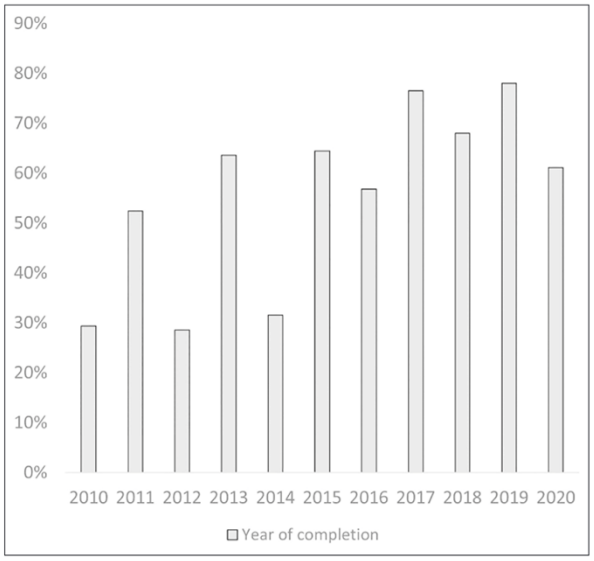
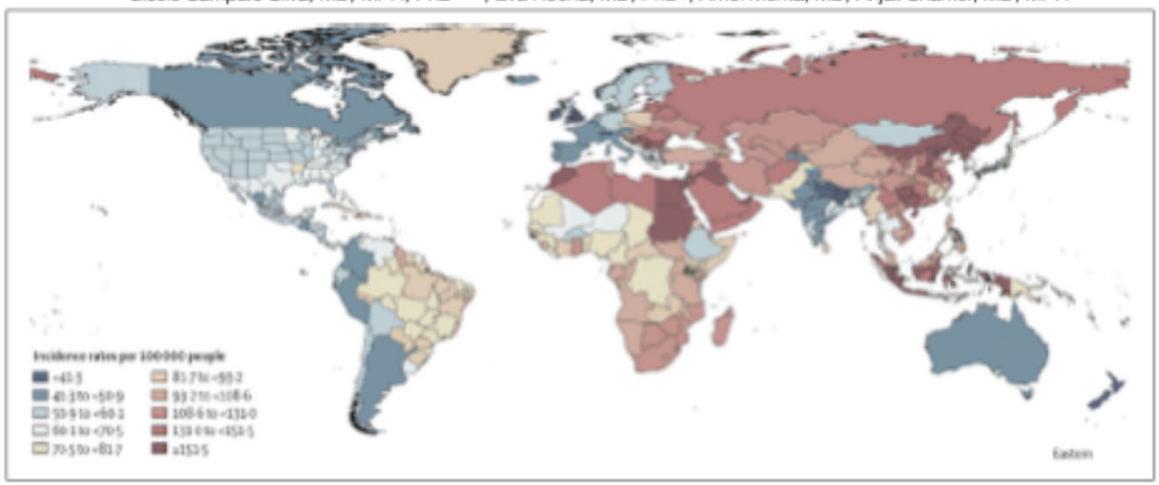


Figure 2. Proportions of stroke trials that reported race distribution, 2010 to 2020.

REVIEW

Racial and Ethnic Diversity in Endovascular Thrombectomy Trials

Gisele Sampaio Silva, MD, MPH, PhD†; Eva Rocha, MD, PhD†; Amol Mehta, MD; Anjail Sharrief, MD, MPH



Silva GS, Rocha E, Mehta A, Sharrief A. Racial and Ethnic Diversity in Endovascular Thrombectomy Trials. *Stroke: Vascular and Interventional Neurology*. 2024;4(1):e000613. doi:10.1161/SVIN.123.000613

Nanavati HD, Andrabi M, Arevalo YA, Liu E, Shen J, Lin C. Disparities in Race and Ethnicity Reporting and Representation for Clinical Trials in Stroke: 2010 to 2020. *J Am Heart Assoc*. 2024;13(6):e033467. doi:10.1161/JAHA.123.033467

Diversity in clinical stroke trials

Journal of the American Heart Association

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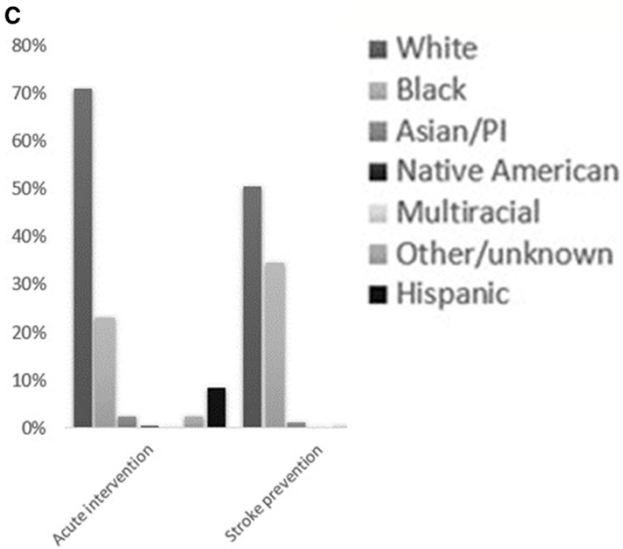


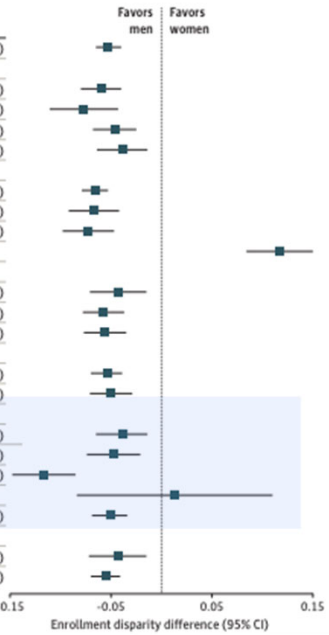
JAMA Neurology | Original Investigation

Sex Disparities in Enrollment in Recent Randomized Clinical Trials of Acute Stroke
A Meta-analysis

Brent Strong; Julia Pudar, BS; Amanda G. Thrift, PhD; Virginia J. Howard, PhD; Murtaza Hussain, MD; Cheryl Carcel, MD, PhD; Gustavo de los Campos, PhD; Mathew J. Reeves, BVSc, PhD

Figure 3. Forest Plot With the Random-Effects Pooled Enrollment Disparity Differences for All Trials and Trial Subgroups

Subgroup	Enrollment disparity difference (95% CI)
Overall	-0.053 (-0.065 to -0.040)
Region	
Americas	-0.060 (-0.080 to -0.040)
Asia Pacific	-0.077 (-0.111 to -0.043)
Europe	-0.046 (-0.068 to -0.025)
Multiregion	-0.039 (-0.064 to -0.014)
Stroke type	
AIS or TIA	-0.066 (-0.079 to -0.053)
ICH	-0.067 (-0.092 to -0.042)
Mixed	-0.073 (-0.098 to -0.047)
SAH	0.117 (0.084 to 0.150)
No. of patients in sample	
<250	-0.043 (-0.071 to -0.015)
250-750	-0.058 (-0.078 to -0.037)
>750	-0.056 (-0.077 to -0.035)
Industry involvement	
Yes	-0.054 (-0.070 to -0.039)
No	-0.050 (-0.071 to -0.029)
Intervention type	
Endovascular therapy	-0.039 (-0.065 to -0.014)
Intravenous thrombolysis	-0.048 (-0.074 to -0.021)
Secondary prevention	-0.117 (-0.148 to -0.085)
Surgery	0.013 (-0.084 to 0.110)
Other	-0.051 (-0.069 to -0.034)
≥1 Women in a leadership role	
Yes	-0.043 (-0.072 to -0.015)
No	-0.055 (-0.070 to -0.041)



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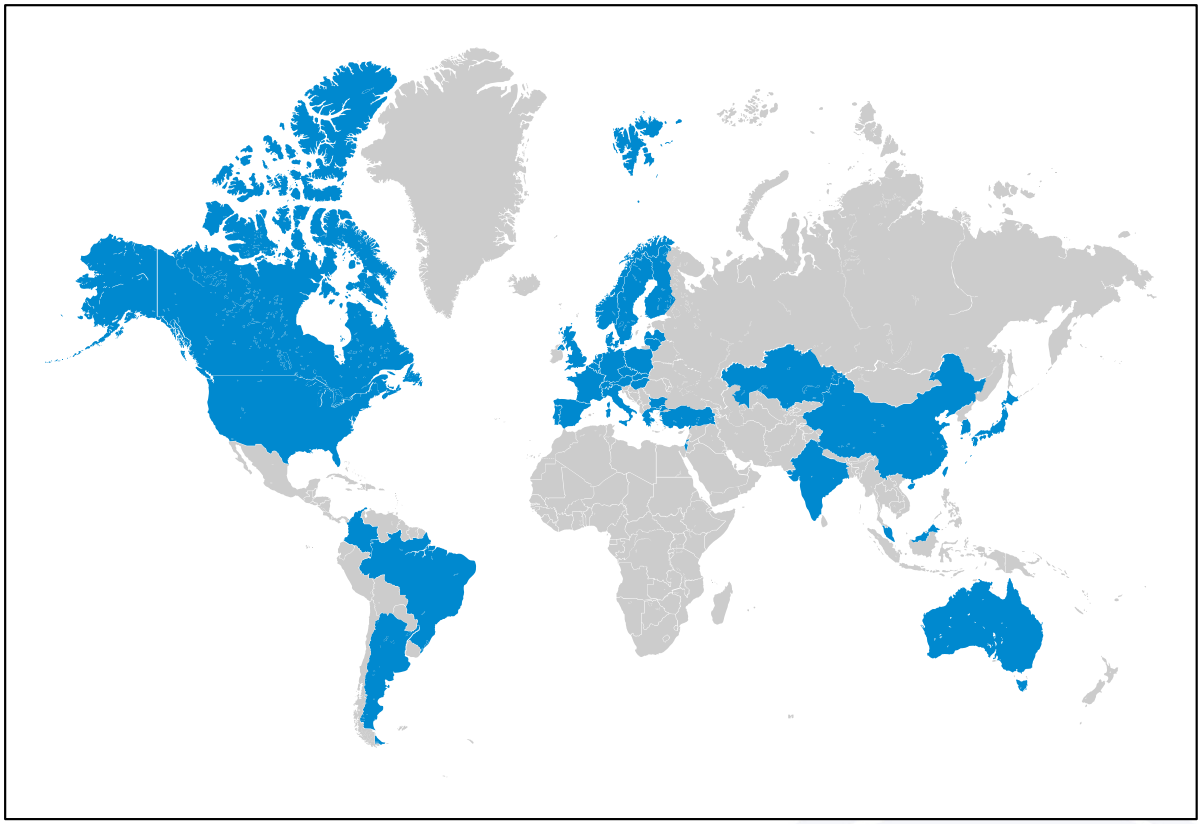
Strong B, Pudar J, Thrift AG, et al. Sex Disparities in Enrollment in Recent Randomized Clinical Trials of Acute Stroke: A Meta-analysis. *JAMA Neurol*. 2021;78(6):666-677. doi:10.1001/jamaneurol.2021.0873

OCEANIC-STROKE

- OCEANIC-STROKE is a placebo-controlled, double-blinded, event-driven, phase III randomized trial
- Comparing oral asundexian 50 mg OD and placebo in participants with acute non-cardioembolic ischemic stroke or high-risk TIA treated with antiplatelets
- Patients were enrolled in 37 countries



OD, once daily; TIA, transient ischemic attack.

Background

- Stroke secondary prevention trials commonly underrepresent women, older adults, and ethnic minorities, compromising the generalizability of findings.
- Reasons for under-enrollment or non-participation of underrepresented groups are not well understood.
- The FIT (Factors Influencing Participation) sub-study, embedded within the international phase 3 OCEANIC-STROKE trial, aims to investigate barriers and facilitators to participation in a multinational stroke prevention trial.

Methods

- FIT-PATIENT is a sub-study started approximately 2 years after the start OCEANIC-STROKE study and was open for enrollment for 5 months.
- FIT-PATIENT is a cross-sectional observational sub-study of OCEANIC-STROKE conducted at 38 sites in 9 countries and enrolled participants approached for consent in the main trial.
- Demographics, clinical variables, socioeconomic factors, and healthcare access factors were collected in a REDCap database at one visit.
- Reasons for non-participation were obtained in those who declined the main trial.
- Descriptive statistics were used to explore differences between those who chose to participate in the trial and those who did not and reasons for non-participation.

Patient Questionnaire V1.0

PATIENT QUESTIONNAIRE

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5. Is tr
No
Yes

- Consent
- Substitute decision-maker
- Living Arrangement
- Transportation difficulties
- Occupational Status
- Education
- Language
- Reason for non-participation

6. Occupational status prior to index event

Employed full-time
Employed part-time
Unemployed

10. Did the patient consent to participate in OCEANIC-STROKE?

No
Yes

Add variables -

PATIENT DEMOGRAPHICS

1. Patient sex at birth

- ○ Male
- ○ Female
- ○ Prefer not to say

Sex at birth

Gender diferente for sex at birth

Age

Ethnicity

Health Insurance

Marital Status

Thrombolysis

EVT

NIHSS upon arrival

Able to walk

Comorbidities

7. Marital status

- ○ Married/Common law
- ○ Divorced/Separated
- ○ Widowed
- ○ Never married

8. Thrombolysis

- ○ No

- ☐ congestive heart failure (CHF)
- ☐ chronic obstructive pulmonary disease (COPD)
- ☐ chronic renal failure
- ☐ cancer
- ☐ cognitive impairment
- ☐ depression

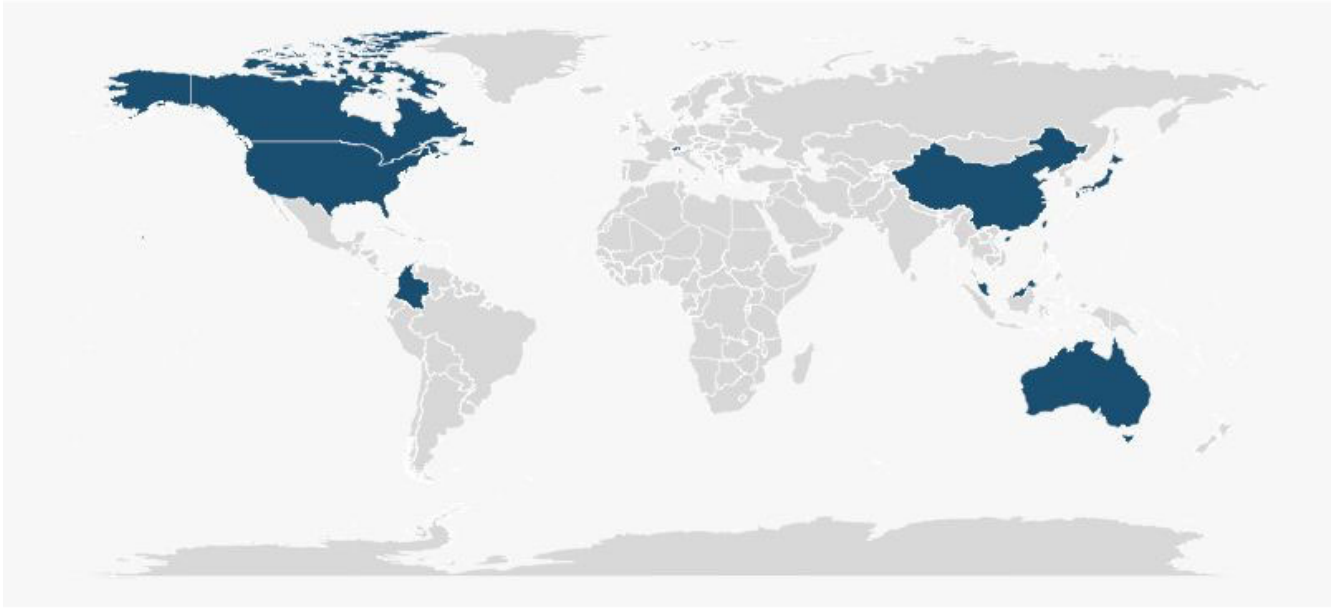
Version 1.0 Date 2024-05-16

Results

139 participants recruited

- 109 consented to participate in the main OCEANIC-Stroke trial
- 30 declined participation in the main OCEANIC-Stroke trial

FIT Study Participating Countries



Results

	Overall	Consented to participate in OCEANIC-STROKE	Declined Participation in OCEANIC-STROKE
Recruited (n)	**139**	**109**	**30**
Age (n, SD)	68.1 (12.5)	67.2 (12.4)	71.6 (12.5)
Male (n)	82 (59.0%)	64 (58.7%)	18 (60%)
Female (n)	57 (41.0%)	45 (41.3%)	12 (40%)

- Among those who were approached, 18/82 (21.95%) males and 12/57 (21.1%) females declined participation into the main OCEANIC-Stroke trial. Therefore, when approached, females had the same likelihood of declining participation as males.

Results

	Total	Participation	Non-participation
	N=139	N=109	N=30
Age, mean (SD)	68.1 (12.5)	67.2 (12.4)	71.6 (12.5)
Females, N(%)	57 (41.0%)	45 (41.3%)	12 (40.0%)
Substitute decision-maker, N (%)	15 (10.8%)	11 (10.1%)	4 (13.3%)
Higher education, N(%)	114 (82.0%)	86 (78.9%)	28 (93.3%)
Current employed, N(%)	57 (41.0%)	48 (44.0%)	9 (30.0%)
Living alone, N(%)	34 (24.5%)	27 (24.8%)	7 (23.3%)
Married, N(%)	89 (64.0%)	69 (63.3%)	20 (66.7%)
Full health insurance, N(%)	109 (78.4%)	82 (75.2%)	27 (90.0%)
White race, N(%)	71 (51.1%)	51 (46.8%)	20 (66.7%)
Transportation difficulties, N(%)	41 (29.9%)	28 (25.7%)	13 (46.4%)
Difficulty ambulating, N(%)	41 (29.5%)	32 (29.4%)	9 (30.0%)

Results

Reasons for declining participation	n
Concern about receiving study drug	25
Unable to commit to follow-up	13
Unable to travel	10
Overwhelmed	9
Not interested	5
Concern about inability to choose intervention	5
Uncertain about participating	5
Work responsibilities	<5
Family refusal	<5
Multiple medical comorbidities	<5
In denial about medical condition	<5
Caregiving responsibilities	<5
Other (ie. frailty, medication burden)	<5
Unknown	<5

Discussion

- Older people were more likely to decline involvement in OCEANIC-Stroke trial
- There were more males than females in FIT-Patient, which may reflect entry pathways for trial inclusion, or fewer females being approached.
- However, once approached, females and males had a similar rate of consenting for trial participation, compatible with prior studies.
- The study is limited by small numbers, participarly those who declined OCEANIC-Stroke, as patients who declined involvement in the main trial would be more likely to decline FIT-Patient sub-study. The small sample limits the assessment of race differences but those with white race were more likely to decline participation compared to others.

Bullet points - possible reason

Conclusions

- Embedding a pragmatic substudy to identify and evaluate barriers to participant inclusion is feasible in a stroke secondary prevention trial, since it can leverage existing screening/consent workflows and routine data capture with minimal disruption to the host study.
- Designing trials to increase engagement of female participants (i.e.. broad inclusion criteria), understanding the needs of older participants, and supporting concerns around study drug, follow-up, and travel difficulties may increase diversity of enrollment into stroke clinical trials.
- FIT-PATIENT is a first step into generating insights to enhance diversity and equity in stroke research and to inform future trial designs, helping ensure that stroke care advances are both evidence-based and broadly applicable across patient populations.