

Background

Randomized controlled trials (RCTs) provide the strongest evidence of efficacy for medical interventions. However, a major criticism about the external validity of RCT results is the underrepresentation of women. Previous studies on cardiovascular disease have found female representation in secondary prevention RCTs to be less than 30%¹. This underrepresentation of women can lead to suboptimal conclusions regarding their care. Currently, limited data are available regarding successful recruitment strategies for women in RCTs. Previous studies suggest that increasing staff availability and fostering a strong rapport through trust, communication and education can enhance the recruitment of women in research².

Purpose

This project aims to examine the influence of gender and recruitment strategies of the research team on the gender of trial participants recruited into Canadian sites participating in NAVIGATE ESUS.

Methods

Canadian NAVIGATE ESUS research coordinators and Investigators were invited to participate in an online survey regarding their opinion recruiting into NAVIGATE ESUS. Surveys were analyzed to determine what staff members, in the opinion of the respondent, were most critical to the participants' decision to join the study as well as the key resources used and perceived barriers to female recruitment.

Results

Canadian NAVIGATE ESUS enrollment of females was 42%, which was comparable to global female enrollment (40%). In our sample, we received 30 survey responses which represented 78% of Canadian NAVIGATE ESUS sites who accounted for 84% of Canadian NAVIGATE ESUS participants. 77% of survey respondents were female. The average enrollment of female NAVIGATE ESUS participants at each responding site was 42% (± 15) and the total weighted average was 43%. Female enrollment at surveyed sites ranged from 17-87%.

Table 1: Characteristics of the most critical staff member in the participants' decision to join the study as reported by the opinion of NAVIGATE ESUS site staff responding to the Survey. Full sample set, top responses are highlighted.

Survey Question	Response	% of Survey Responses describing the Most Critical Staff Member	% of Survey Responses describing the 2nd Most Critical Staff Member
Role	Principal Investigator	69	14
	Study Coordinator/Nurse	24	65
	Other	7	21
Age	20-29yrs	0	7
	30-39yrs	24	31
	40-49yrs	34	48
	50-59yrs	17	10
	60+yrs	24	3
Gender	Female	57%	73%
Overall % involvement in randomization	0-25%	32	14
	26-50%	18	24
	51-75%	21	24
	76-100%	29	38
Average time spent with each subject during consent	0-15min	28	10
	15-30min	41	36
	0.5-1hr	14	36
	1-2hrs	14	18
	2+hrs	3	0
Involvement in the consent process	Approach the potential subject	24	18
	Review the ICF	17	20
	Answer non-medical questions about the study	15	22
	Answer medical questions about the study	30	20
	Obtain consent	14	20
	Other	1	0

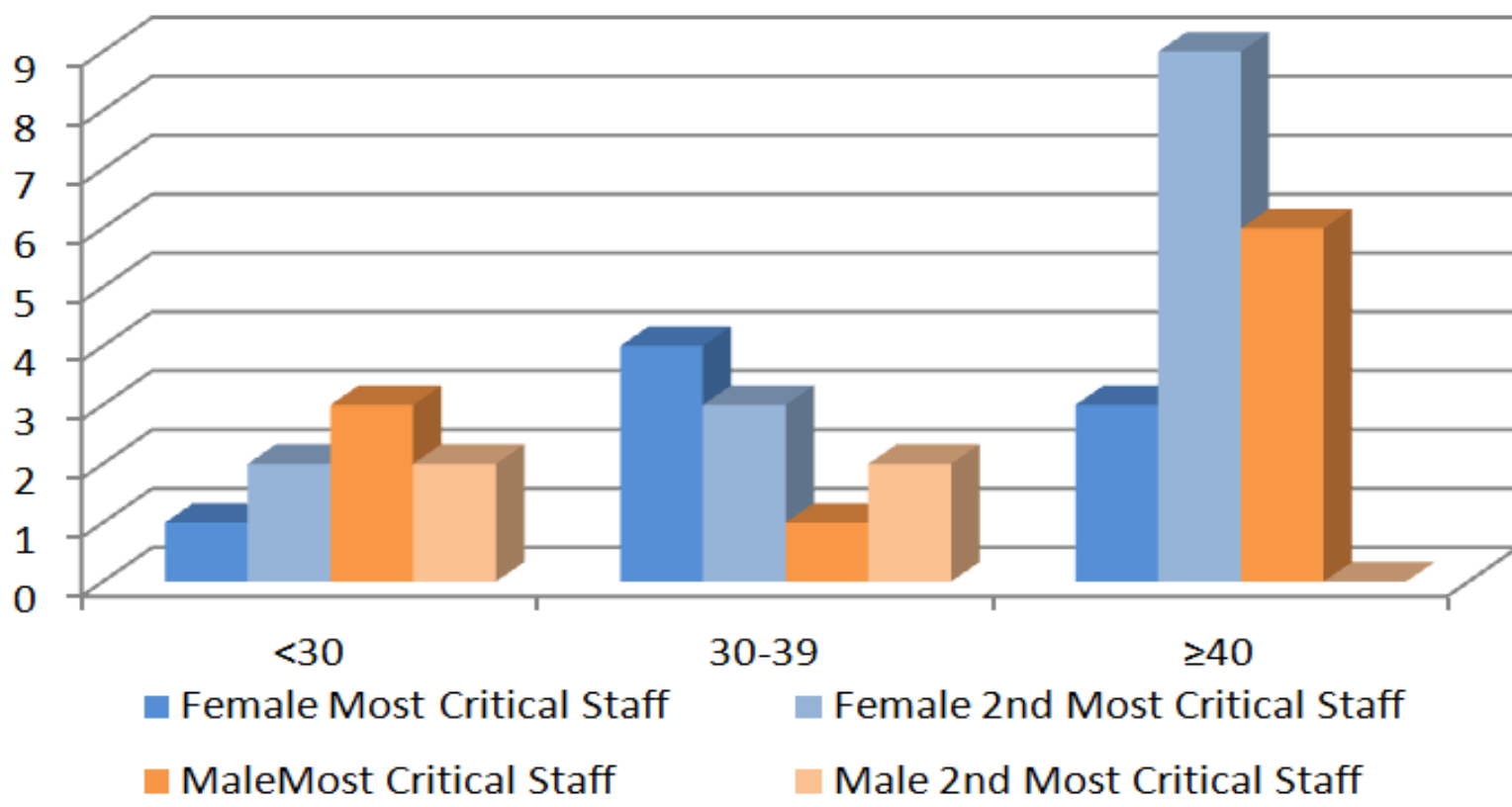


Figure 1: Frequency of Gender of Most Critical Staff by Percent of Female Enrollment at the Responding Site. Duplicate Site Responses Removed.

During the conduct of NAVIGATE ESUS, what resources did you use that you think were most critical in the patients' decision to join the study at your site?

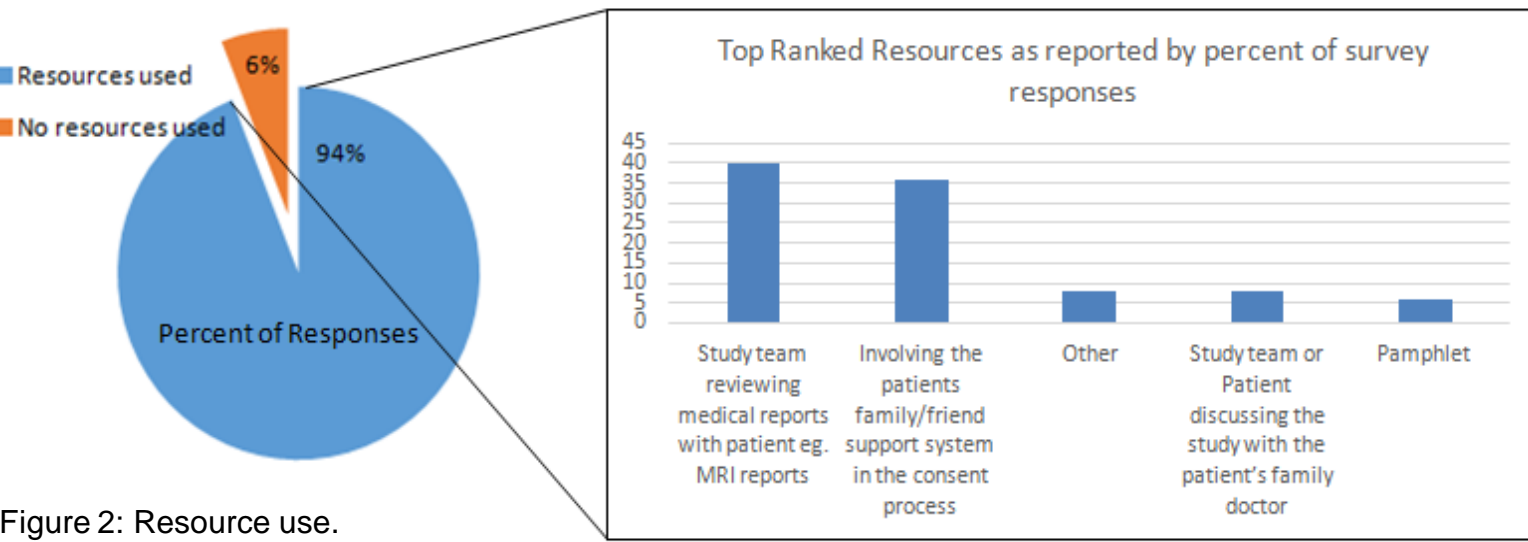


Figure 2: Resource use.

In your opinion what were the top two barriers to enrolling females into NAVIGATE ESUS?

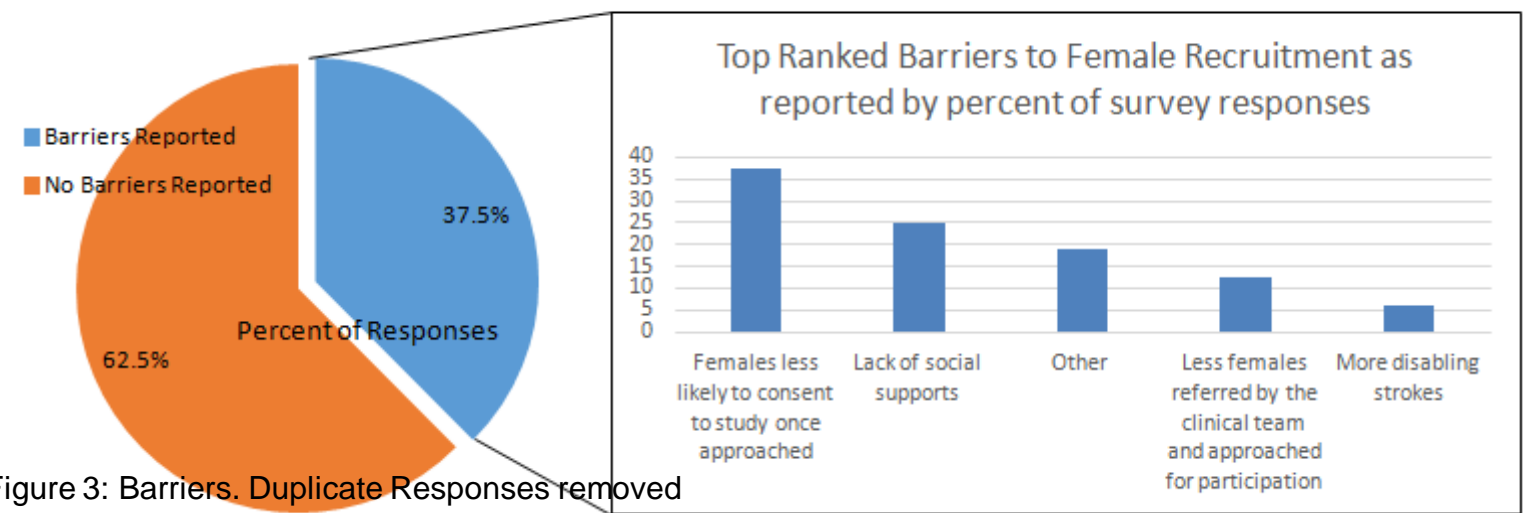


Figure 3: Barriers. Duplicate Responses removed

Key Findings

Previous registry data indicates 43% of Canadian ESUS patients are women³. The results of our analysis suggests that females were appropriately represented in the Canadian NAVIGATE ESUS population. A categorical reflection of site staff gender by percent female participants suggests that sites with more female participants were more likely to have a female second most critical staff member (Figure 1), however it is important to note that the distribution of staff gender in this analysis was predominantly female (Table 1). Our results show that the majority of sites in Canada utilized resources during informed consent (Figure 2) and reported no barriers to enrolling females into NAVIGATE ESUS (Figure 3).

Discussion

The use of an opinion based survey, administered after study close out in one country for one study, has significant limitations. It is possible that the results obtained in this analysis over represent involvement of female site staff as 77% of respondents were female.

Conclusion

Our preliminary results support the notion that female recruitment may be enhanced by the presence of female site staff and the use of resources during the consent process. Future RCTs could more accurately assess this finding by prospectively collecting basic demographics of site staff and utilizing screening logs to assess participant gender and reason for exclusion.

References

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3. Perera, K.S., Vanassche, T., Bosch, J., Giruparajah, M., Swaminathan , B., Mattina, K.R...Hart, R.G. (2016). Embolic strokes of undetermined source: Prevalence and patient features in the ESUS Global Registry. *International Journal of Stroke*, 5, 526-33.