Comparison of Patient Recruitment Methods: Use of Advocacy Organizations and Clinical Sites in Migraine Studies

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Background & Objectives

- The Migraine Clinical Outcome Assessment System (MiCOAS) is an FDA-funded research program integrating patient input into clinical trial assessments
- A key research concern is whether study enrollment achieves a sample representative of important population characteristics such as demographics or headache frequency. Over three qualitative interview studies, we recruited via headache and neurology clinics (Sites) and patient advocacy organizations (PAO) associated with the Coalition of Headache and Migraine Patients (CHAMP) and compared results

Methods

- ***PAO recruitment***: PAOs distributed IRB-approved outreach messages via newsletters and social media. Select messages appealed for males and people of color, as these populations have been under-represented in migraine research; some messages included photos or mentioned study compensation. Dates of enrollment were compared to dates of message delivery by PAOs. Numbers of participants who completed study activities (screening, survey, interview) were tabulated
- ***Site recruitment***: Sites used IRB-approved case report forms to determine eligibility and were asked to meet targets for episodic/chronic migraine (EM, CM) and for males, people of color, and Hispanic people. For each participant, data were examined to determine whether all enrollment steps and study activities were completed

Table 1. Comparison of Key Sample Characteristics

Characteristic	Study 1 (PAO, n=31)	Study 2 (PAO, n=17)	Study 3 (Sites, n=34)
Male	9 (29%)	5 (29%)	5 (15%)
American Indian/Alaska Native	3 (10%)	0 (0%)	0 (0%)
Asian	1 (3%)	2 (12%)	0 (0%)
Black/African American	6 (19%)	4 (24%)	15 (44%)
Native Hawaiian/Pacific Islander	0 (0%)	0 (0%)	0 (0%)
White	18 (58%)	10 (59%)	18 (53%)
Other Race	4 (13%)	2 (12%)	1 (3%)
Hispanic	6 (19%)	5 (29%)	5 (15%)
Episodic migraine	18 (58%)	8 (48%)	15 (44%)
Chronic migraine	13 (42%)	9 (52%)	19 (56%)

Results

- ***Enrollment Results***: 427 people were recruited via PAOs and signed the informed consent; 342 (80%) filled out the survey. From this pool, 59 were selected and contacted about interviews: 11 (19%) were unresponsive or were repeat no-shows for scheduled interviews, and 48 (81%) completed interviews.

  Across 5 Sites, 72 people signed the informed consent and 50 (69%) completed the survey. Sites did not upload case report forms for 3 (6%) participants, for a total enrolled sample of 47. From this pool, 13 (28%) were unresponsive or repeat no-shows for scheduled interviews and 34 (72%) completed interviews
- ***Representativeness of the Sample***: Recruited samples were similar across many key characteristics (Table 1). Key differences included improved recruitment via PAO of male, Hispanic, Asian, and Indigenous/Other Race participants, while Sites achieved improved recruitment of Black/African American participants. However, overall enrollment of Asian, Indigenous, and Other Race participants was limited across both recruitment methods.

Table 2. Comparison of Recruitment Method Results

	Recruit Method Used	# Interviews Completed	Recruitment Start Date	Recruitment End Date	Total Elapsed Time	Recruiting Days Per Interview
Study 1	PAO	31	Aug 3, 2021	Sept 21, 2021	49 days	1.6
Study 2	PAO	17	Feb 1, 2023	Feb 20, 2023	19 days	1.2
Study 3	Sites	34	May 5, 2022	May 31, 2023	391 days	11.5

- ***Recruitment Costs***: The total cost of recruitment via Sites resulted in a cost per participant approximately 4.3 times higher than when using a PAO.
- ***Enrollment Time***: Total elapsed time for recruitment was different for each method, taking over 1 year for recruitment via Sites compared with 3 weeks to 2 months for recruitment via PAO (Table 2). Data for PAO recruitment showed that social media posts targeting under-represented populations or mentioning compensation were associated with a bump in enrollment occurring 2-7 days later (see example in Figure 1). The largest increases in total recruitment occurred on weekdays (Tuesday to Friday)

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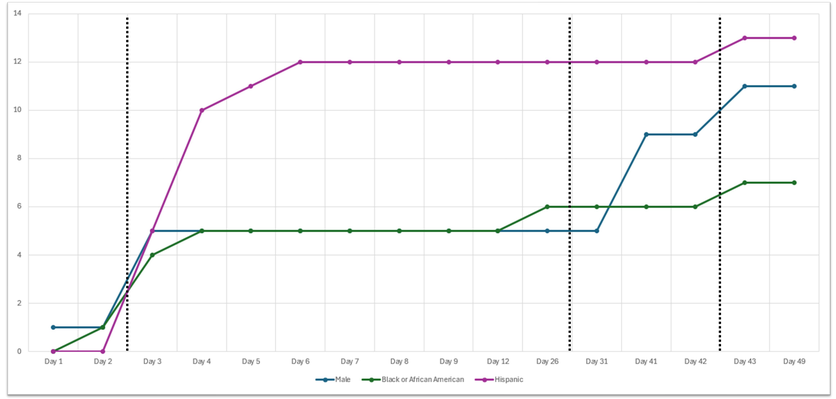
Figure 1. Cumulative response to recruitment by under-represented groups (study 1)



Vertical lines indicate days targeted messages were disseminated by PAOs

Conclusions

Recruitment via PAO provided a large, diverse group of eligible participants at a faster pace and lower cost than Site recruitment. Release of targeted study announcements was followed by a spike in recruitment of males and people of color, although overall response remained low. Recruitment via sites also resulted in a diverse group of eligible participants and provided assurance that participants had a confirmed migraine diagnosis but took longer and was more costly.

These findings underscore important tradeoffs in using these recruitment methods in observational studies. Depending on study aims and resources, use of multiple recruitment methods may result in the best available pool of eligible participants, including access to needed numbers of under-represented population groups. These findings apply to studies where a prescriber is not required.

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