

Leave me out!: Patients’ characteristics and reasons for opting out of a pragmatic clinical trial

Nudge

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BACKGROUND

- Pragmatic clinical trials (PCT) inform healthcare decisions based on data from real-world populations, requiring data be collected from a large, representative populations.
- Opt out consent practices are increasingly used to obtain consent while reducing patient and researcher burden. Despite this, little is known about patients who opt-out.
- Our objective is to describe the opt out process developed and employed for a large, multi-center, text-based PCT regarding medication adherence, the characteristics of patients who opted out, and their reasons for doing so.

STUDY POPULATION

Patients from the VA Eastern Colorado Health Care System and Denver Health and Hospital Authority aged 18 – 89, diagnosed with ≥ 1 cardiovascular condition and prescribed ≥ 1 medication to treat the condition(s) were included. Patients that did not speak English or Spanish, have a cell phone or home address on file, or reside in the State of Colorado were excluded.

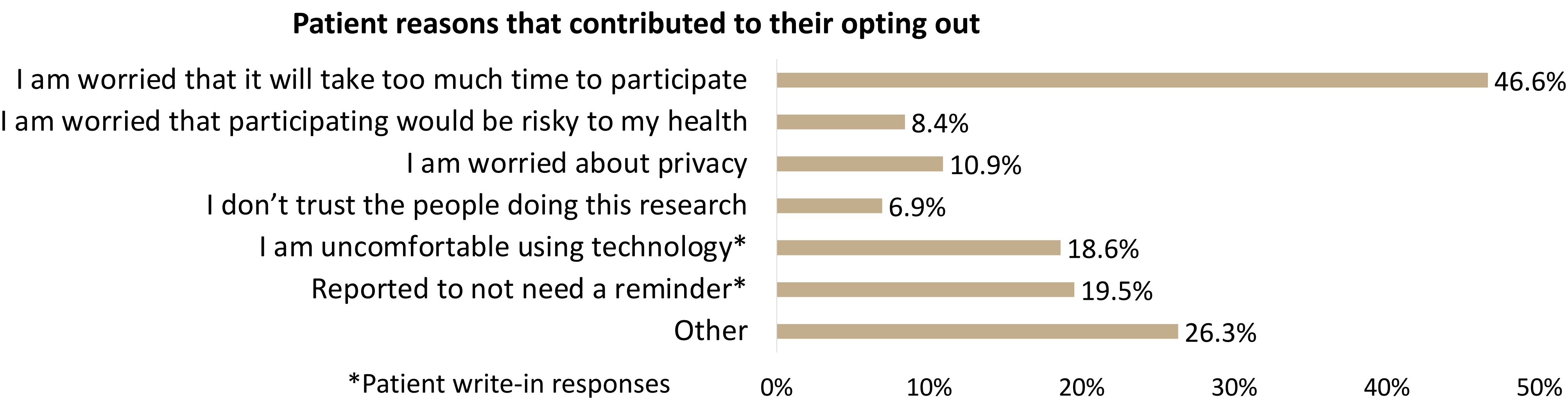
METHODS

- Eligible patients identified through Electronic Health Records were sent informational material about the study and provided an opportunity to opt out. Those who opted out were asked to complete a voluntary, anonymous survey regarding their reasons for choosing not to participate.
- Demographic data and reasons for opting out were compared with enrolled patients using chi-squared tests.

RESULTS

Of 9,444 patients eligible for the trial, 895 (9.5%) patients opted out between 10/1/19 and 9/1/20. Among those who opted out, 50.1% returned the opt out survey.

	Opt-out population N = 895	Enrolled population N = 8187	p		Opt-out population N = 895	Enrolled population N = 8187	p
Age			<0.001	Gender, female	0.641 (574)	0.542 (4434)	<0.001
0 to 40	0.016 (14)	0.063 (517)		Race			<0.001
41 to 50	0.042 (38)	0.146 (1192)		White	0.763 (683)	0.723 (5919)	
51 to 60	0.141 (126)	0.262 (2144)		Black	0.136 (122)	0.16 (1309)	
61 to 70	0.359 (321)	0.306 (2506)		Multiple	0.004 (4)	0.008 (68)	
71 to 80	0.335 (300)	0.175 (1435)		Other	0.054 (48)	0.092 (755)	
81+	0.107 (96)	0.048 (393)		Hispanic, yes	0.332 (297)	0.542 (4436)	<0.001



CONCLUSIONS

In this PCT focused on medication adherence improvement, less than 10% of patients opted out of participation, with significant differences in age, race, gender, and ethnicity between patients that opted out vs. those that did not. Future opt out trials may wish to provide additional information to address the most commonly cited reasons by patients for opting out of a low-risk trial. Our future research plans include examining additional patient characteristics, including trust measures and history of research participation.

