

Exploring Patients' Perceptions of Clinical Research in Inflammatory Bowel Disease and Barriers to Participating in Clinical Trials

Kelly Chatten¹; Philip Kalra^{1,2}; Peter Bower²; John McLaughlin^{1,2}; Subrata Ghosh^{3,4}; Jimmy K Limdi^{1,2}

¹Northern Care Alliance NHS Foundation Trust, United Kingdom, ²University of Manchester United Kingdom, ³Biomedical Research Centre Birmingham, University of Birmingham, ⁴University Hospitals Birmingham NHS Trust, United Kingdom.

Introduction

Despite the rising incidence and prevalence of inflammatory bowel disease (IBD), participation in research in IBD remains relatively low.

Aims of the proposed research

1. To explore perceptions of research and barriers to participation
2. To assess patient knowledge and awareness of types of research.
3. To explore factors that might motivate people to participate in research

Methods and Materials

We developed a questionnaire along with a focus group of people living with IBD. Patients with IBD attending office visits, endoscopy and infusion units, at our centre were invited to complete a questionnaire in person, or electronically. Demographics, disease duration and activity were recorded and perceptions and barriers to participating in research were explored.

		Would participate			Would not participate			Declined to complete
Sex	Male	45.7%			58.6%			70%
	Female	54.3%			41.4%			30%
Duration of disease	Median	5-9 years			5-9 years			
	Age	35-44 years			45-54 years			35-44 years
Scores	PMAYO	MEAN	MEDIAN	MEAN	MEDIAN			
	HBI	2.0	1.0	2.75	2			
Patient rated IBD control /10	Yes	No	Not sure	Yes	No	Not sure		
		7.1	7.5	5.9	5.0			
		33.0%	63.7%	3.3%	44.8%	44.8%	10.3%	
Admission	Yes	No	Not sure	Yes	No	Not sure		
	16.2%	82.5%	1.3%	20.7%	79.3%	0.0%		
On biologics/small molecule	Yes	No	Yes	No				
	65.0%	35%	51.7%	48.3%				

Table 1. Demographics and disease characteristics in participant groups

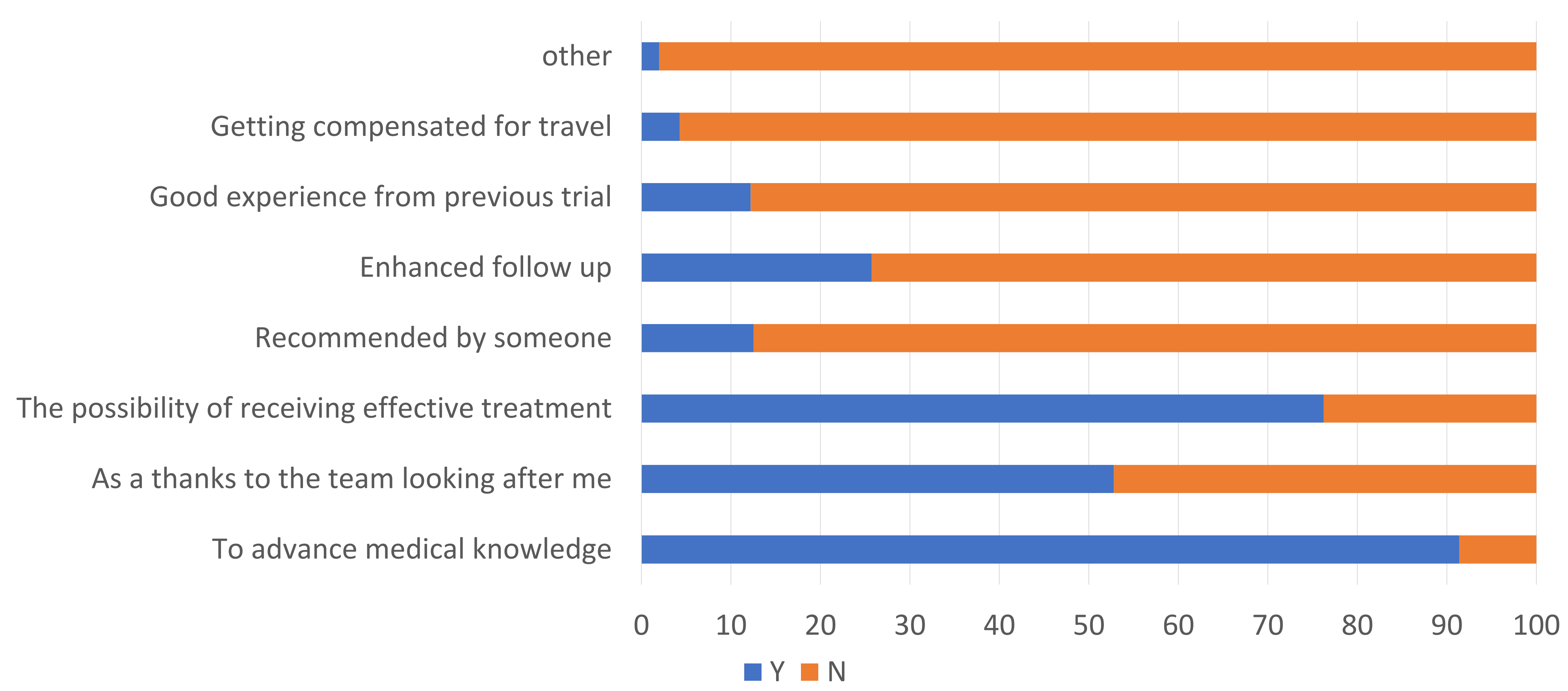


Chart 1. Reasons participants would be interested in future research (%) .

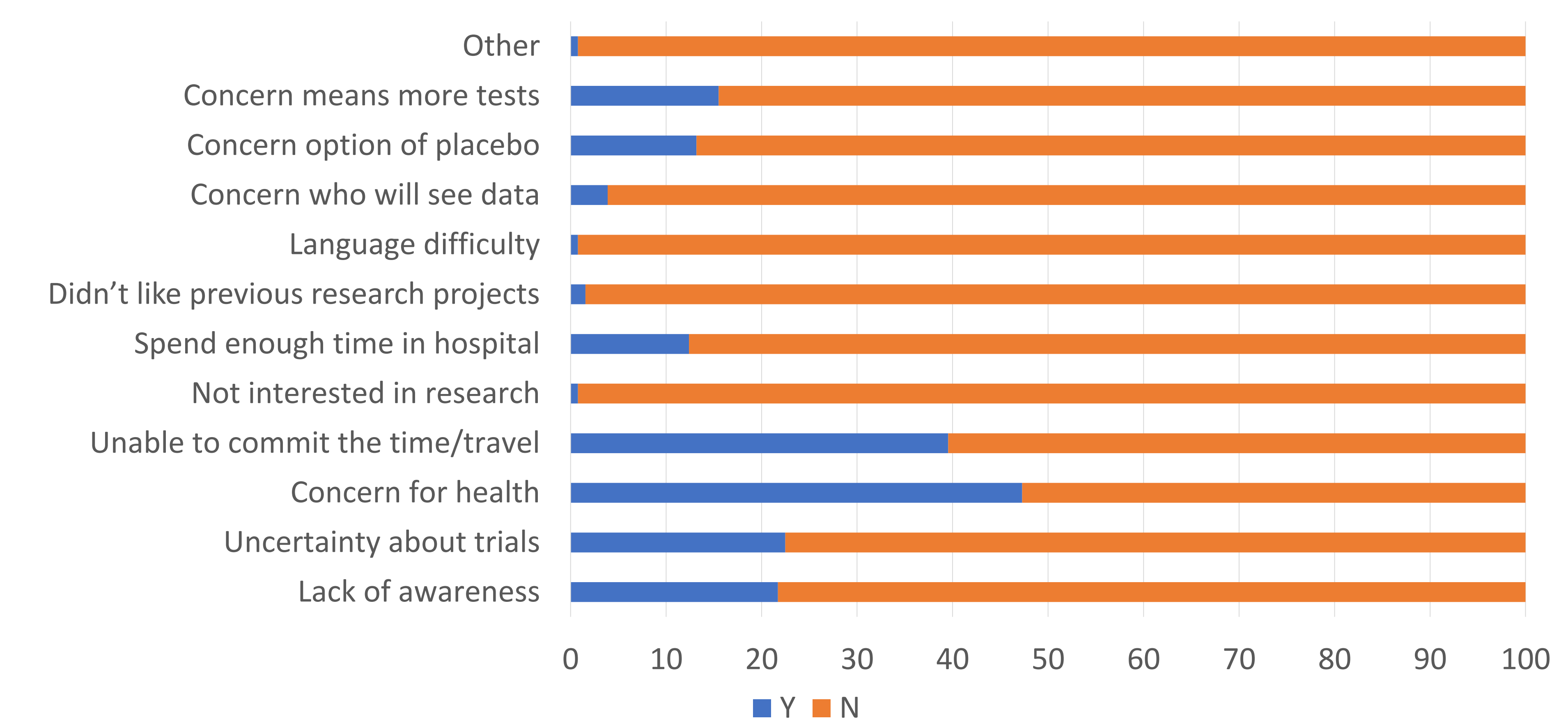


Chart 2. Reasons participants would not be interested in future research.

Results

Among 392 patients (197/391 50.4% were female, 194/391, 49.6% were male, 1 did not answer) 164/332 (49.4%) had CD, 147/332 (44.3%) UC, 8 (2.4%) had IBD U and 13 (3.9%) were unsure of their diagnosis. More females (176/331, 54.3%) expressed willingness to participate (table 1).

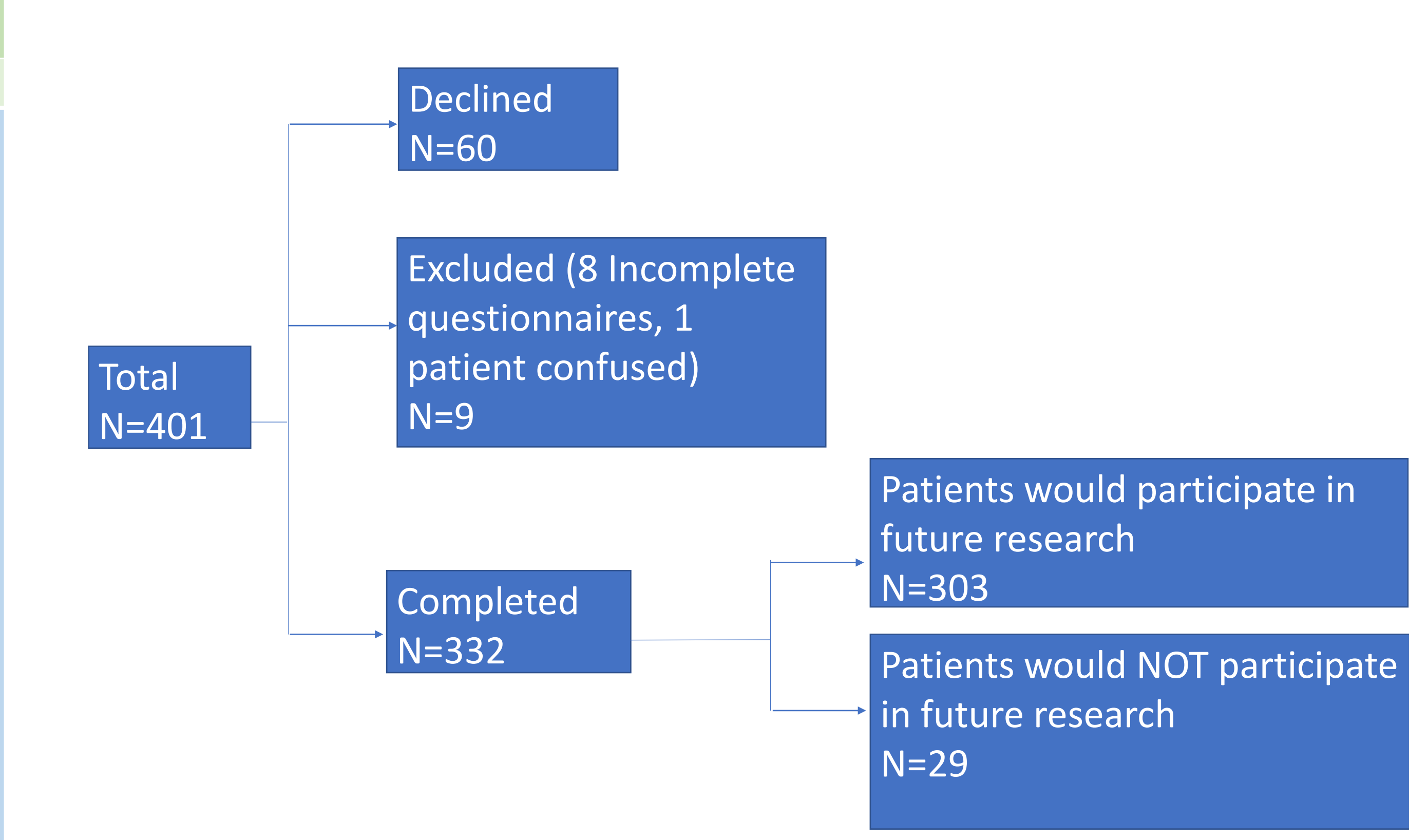


Figure 1. Number of patients approached and their responses

Results

Average pMayo and HBI were slightly higher in those that did not want future research participation and disease control was rated worse overall. They had higher steroid use, hospital admission and immunomodulator use (6/29, 20.7% vs 39/303, 12.9%). Use of biologics/small molecule therapies was lower (table 1). 191/122 (63%) would be interested in drug trials, 281/303 (92.7%) in questionnaires and 198/303 (65.3%) in new investigations). The most common reason for participation in research was “to advance medical knowledge” (see chart 1). For those not wishing to participate in further research the most cited barrier was “Unable to commit the time/travel “ (17/29 58.6%) (chart 2) as well as being the most important reason (14/29, 50.0%). Among those responding to the optional question of barriers to participation (100/303 (33%) answered) the most common barrier was concern for own health (54/100, 54.0%) followed by time commitment(34/100, 34%). Direct conversation with their doctor was the most likely action for both groups to participate in research (12/29, 41.4% and 189/303, 62.4%). For those interested in research access to new drugs was also rated highly (112/303, 37.0 compared with 3/29 10.3%).

Discussion

The majority of patients approached completed the questionnaire and would be interested in future research. Most who did not want to participate in research rated disease control lower. The majority of patients were interested in advancing medical knowledge in keeping with the high uptake of this questionnaire. Both groups felt time commitment was a major barrier. Many patients with IBD are of working age or with young families which likely impacts on time availability(1). Placebo and more tests were not rated as significant compared to studies from the USA, however they referred specifically to clinical trials and endoscopy(2–4).

Conclusions

Patients express high level of interest in research engagement. Improved communication to allay potential fears regarding risk and improved pathways to minimize their time commitment are important factors to patients.

References

1. Ehrlich O, Testaverde J, Heller C, et al. Crohn's disease and ulcerative colitis patient perspectives on clinical trials and participation [Internet]. medRxiv 2019;19000273.[cited 2022 Oct 3] Available from: <https://www.medrxiv.org/content/10.1101/19000273v1>
2. Ravikoff JE, Cole EB, Korzenik JR. Barriers to Enrollment in Inflammatory Bowel Disease Randomized Controlled Trials: An Investigation of Patient Perspectives [Internet]. Inflamm. Bowel Dis. 2012;18:2092–2098.[cited 2022 Oct 3] Available from: <https://academic.oup.com/ibdjournal/article/18/11/2092/4608937>
3. Schreiber S, Irving PM, Sharara AI, et al. Review article: randomised controlled trials in inflammatory bowel disease-common challenges and potential solutions [Internet]. Aliment. Pharmacol. Ther. 2022;55:658–669.[cited 2022 Oct 3] Available from: <https://pubmed.ncbi.nlm.nih.gov/35132657/>
4. Wood D, Kosa K, Brown D, et al. Preferences of Adult Patients With Inflammatory Bowel Disease for Attributes of Clinical Trials: Evidence From a Choice-Based Conjoint Analysis [Internet]. Crohn's Colitis 360 2020;2[cited 2022 Oct 3] Available from: <https://academic.oup.com/crohnscolitis360/article/2/1/otz048/5645431>

Abbreviations Inflammatory bowel disease (IBD), Parital Mayo score (pMayo), Harvey bradshaw index (HBI)