FACTORS INFLUENCING PARTICIPATION IN RHEUMATOID ARTHRITIS PREVENTION

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Introduction

Recruitment of subjects for clinical prevention studies is complicated by the need for otherwise healthy individuals to assume the inherent risks within clinical research in absence of an active disease (1). The rheumatoid arthritis (RA) field has begun trials in prevention. One trial is StopRA that is evaluating hydroxychloroquine (HCQ) as a preventative treatment for those at high risk of developing RA. The goal of this current study is to evaluate the factors that influence an individual's decision to participate in StopRA to improve future study design and enrollment.

Methods

The Research Participation Influences study is an IRB approved protocol where participants provided written or verbal consent, depending on whether the survey was conducted in person or through a telephone encounter. Individuals found to have elevated ACPAs and those eligible for enrollment in StopRA were first notified of their at-risk status of developing RA, given an overview of the study design and further surveyed about the factors that influenced their decision on whether to participate in StopRA. Along with providing demographic data, through a Likert scale questionnaire, they were asked to rate how much factors like 1. potential influence to their health, 2. potential benefit to their family, 3. potential benefit to others, 4. time requirements for trial, 5. personal risk of developing RA, 6. compensation offered, 7. moral feelings of obligation, 8. potential positive effects of trial medication, 9. potential adverse effects of medication, 10. potential to learn more about RA, or 11. potential of being assigned to the placebo group influenced their decision (2). The results were compiled and statistically analyzed using Fisher exact test for categorical variables, independent sample T test for mean age of participants and Mann-Whitney U test for comparison of responses within the sub-category of those who had first degree relatives (FDR) with RA. Likert scale responses of "Not at all" to "Very much" were converted into an ordinal scale of 0 to 4 respectively, and Chi-square test was used for statistical analysis.

Results

Table 1: Subject Characteristics

	Agree to trial?		
	Yes	No	
	N=30	N=16	P-value
Gender, N (% Female)	22 (73%)	13 (81%)	0.72
Age, mean (SD)	52 (15)	58 (17)	0.78
First degree relatives of patients with RA, N (% Yes)	17 (57%)	2 (13%)	<0.01*
Education, N (% Some College or greater)	27 (90%)	15 (94%)	1.00
Income, N (% $31K or greater)*	19 (63%)	10 (63%)	0.40

* of those who provided answers

Among the general demographics that were surveyed, having First Degree Relatives (FDRs) with RA was the only factor that significantly influenced the decision to participate in the prevention trial.

Table 2: Median Values of Influence on Participation

	Agree to Trial?		
	Yes	No	
Influences	N=25	N=11	P-value
Benefit Me, median (range)	4 (2,4)	1.5 (0,4)	<0.01*
Benefit Family	4 (0,4)	1 (0,4)	0.01*
Benefit Others	4 (2,4)	1 (0,4)	<.0.01*
Time	1 (0,4)	1 (0,4)	0.13
Risk	4 (0,4)	2.5 (0,4)	0.03*
Compensation	1 (0,3)	1 (0,3)	0.52
Moral Obligation	3 (0,4)	2 (1,4)	0.15
Positive Side Effects	3 (1,4)	1 (0,4)	0.02*
Adverse Side Effects	2 (0,4)	4 (0,4)	<0.01*
Learn About RA	3 (0,4)	1.5 (0,4)	0.10
Placebo Potential	1 (0,4)	2 (0,4)	0.41

0=no opinion; 1=not at all; 2=a little; 3=somewhat; 4=very much;

The Likert scale questionnaire revealed that individuals who participated in prevention trials were more likely to do so in order to benefit themselves, their family and society and to potentially gain positive benefits from the medication. Additionally, there was a higher perceived personal risk of developing RA.

Those who declined to participate had significant concerns about the trial medication and its side effects.

Results

Table 3: Median Values of influence on Participation Between Participants With and Without First Degree Relatives with RA

Agree to Trial?	Yes		
	Yes	No	
FDR	N=17	N=13	P-value
Benefit Me, median (range)	4 (2,4)	4 (2,4)	0.54
Benefit Family	4 (1,4)	3 (0,4)	0.03*
Benefit Others	4 (3,4)	4 (2,4)	0.32
Time	1 (0,3)	1 (0,4)	0.84
Risk	4 (2,4)	3 (0,4)	0.02*
Compensation	1 (0,2)	1 (0,3)	0.56
Moral Obligation	3 (0,4)	3 (1,4)	0.68
Positive Side Effects	3 (1,4)	3 (2,4)	0.65
Adverse Side Effects	2 (0,4)	3 (0,4)	0.77
Learn About RA	3 (0,4)	3 (1,4)	0.68
Placebo Potential	1 (0,4)	2 (0,4)	0.59

0=no opinion; 1=not at all; 2=a little; 3=somewhat; 4=very much;

Of those who agreed to enroll in the StopRA trial, we compared motivations of individuals who had and did not have FDRs with RA.

Those who had FDRs were significantly more likely to specifically want to benefit their families through their participation. Additionally, this cohort had a much higher perceived personal risk of developing RA, attributable to the availability heuristic (3, 4).

Limitations

There are many well-documented difficulties with conducting subjective studies, which often have results that are confounded by multiple factors

- Recruitment strategies may not reflect the attitudes of the general population and may skew the results
- Those who declined to both participate in the prevention trial and to take the RPI questionnaire is a separate cohort that could not be assessed (5)
- Likert scales are an imprecise tool of data gathering with a limited scope of responses and are confounded by the desirability bias (6)
- There continue to be difficulties in obtaining, scoring and comparing verbal responses. No standardized conversion of qualitative into quantitative data exists

Conclusions

This study examines the factors that are influential in the individual decision-making process about whether to participate in RA prevention studies. Our findings indicate that individuals who have FDRs with RA are more likely to participate in RA prevention and that this population can be targeted directly to improve recruitment rates. Additionally, wanting benefit to self, family and others were significant factors in the decision to enroll and can be further emphasized in the consent process. Furthermore, the results support that there continues to be public uncertainty and misunderstanding of the clinical research process and efforts should be made to improve education and increasing discourse between physicians and patients in order to minimize perceived risk and increase participation. This approach highlights the multifaceted and complex nature of the decision-making process and provides an opportunity to optimize future study design and recruitment approaches.

References

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*** we have no conflicts of interest to disclose