

# Patients' impressions of a clinical study/clinical trial and factors contributing to the impressions: A questionnaire study

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## Objective

- Our aims are to clarify what patients with rare and intractable diseases and their families think about CTs (Clinical Trials) and whether or not their impressions of CTs differ depending on the presence/absence of participation in CTs

## Method

- Target: Patients with NANBYO (rare disease/refractory disease/long-term chronic disease) or their family members, or other persons concerned
- Procedure: We collected data using online input form in corporation with NANBYO patient associations
- Period: From October 1, 2018 to December 2, 2018
- Analysis: We analyzed the basic characteristics of respondents and examined their impressions of CTs by groups with and without experience of participating in CTs. The relationship between the words used in the responses received was shown graphically, and the degree of positivity/negativity of these words and phrases in the responses was quantified to explore factors contributing to the degree, using multiple regression analysis. Because this survey is an exploratory, the significance level was set at  $p < .10$

## Result

- Valid responses were received from 151 respondents
- Patients who have experience of participating in CTs accounted for about 20% (Table1)

Attribute		N=151 n (%)	
Sex	Male	50 (33.1)	
	Female	100 (66.2)	
	Education	Junior high school	2 (1.3)
		High school	75 (49.7)
University or higher		73 (48.3)	
Duration of disease		0 - 5 years	34 (22.5)
	6 - 10 years	27 (17.9)	
	11 - 15 years	26 (17.2)	
	16 - 20 years	16 (10.6)	
	More	46 (30.5)	
Patient association	Belonging	119 (78.8)	
Participating in a CT	Yes	31 (20.5)	
Receiving an explanation about a CT	Yes	26 (17.2)	

Note. Missing values were excluded

	Estimated values	Standard error	$p$
Sex	< .00	0.05	0.96
Education	0.01	0.01	0.32
Duration of disease	< .00	0.00	0.61
Patient association	0.01	0.06	0.82
Participating in a CT	0.16	0.08	0.06
Receiving an explanation about a CT	-0.04	0.07	0.57
(Constant term)	-0.75	0.18	< .00
Adjusted R <sup>2</sup>	0.03		

Note) Dependent variables: The degree of positivity or negativity of response.

Multiple regression analysis using a forced entry method was performed.

Sex: 1 = Male, 2 = Female

Educational background: Junior high school graduate = 9, High school graduate = 12, University graduate = 16 (Replaced with the number of years of education received)

Duration of disease: 0 to 5 years = 2.5, 6 to 10 years = 7.5, 11 to 15 years = 12.5, 16 to 20 years = 17.5, 21 years or longer = 22.5

Status of belonging to patient association: Not belonging = 0, Belonging = 1

Experience of participation in CTs: 0 = Without the experience, 1 = With the experience

Experience of receiving explanation of CTs: 0 = Without the experience, 1 = With the experience

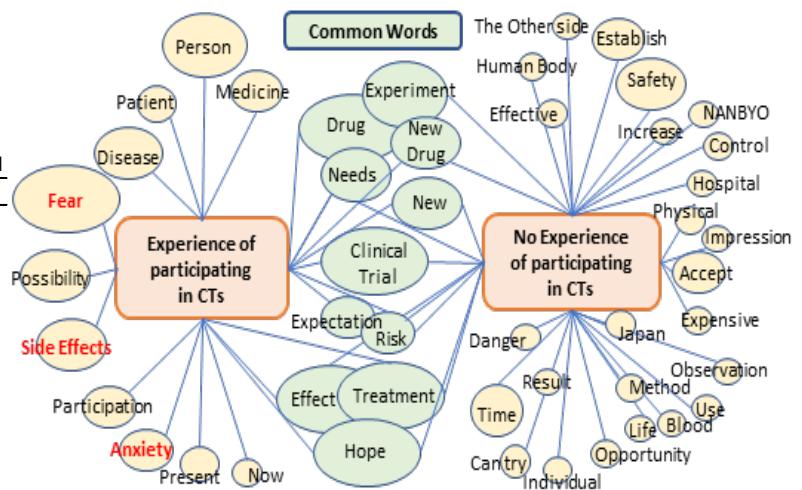


Figure 1. Differences in words used in the response about impressions of CTs

- Words reflecting negative impressions of CTs such as “Side Effects”, “Fear”, and “Anxiety” were commonly found in responses from respondents who had never participated in CTs. (Figure1)

- As a result, sex, educational background, duration of disease, status of belonging to patient association, and presence or absence of experience of receiving explanation of CTs did not significantly contribute to the degree of positivity and negativity of the responses, but it was suggested that the degree of negativity of the response was significantly increased ( $\beta = 0.16$ ,  $p = 0.06$ ) in respondents without experience of participating in CTs. (Table2)

Respondents who have never participated in CTs tend to negatively respond about CTs. It is important to provide correct information to persons who have never participated in CTs so that their questions can be resolved and to always give careful consideration to the anxiety of persons who participate in CTs for the first time. We will inform this result for general public and conduct further research to improve patients' impression of CTs.