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ORIGINAL ARTICLE

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Rheumatic disease patients' motivations and emotions related to the decision to participate in a clinical trial: preliminary findings

ABSTRACT

Background: Clinical trials are extremely important in the development of modern therapies. Unfortunately, it is currently difficult to recruit patients for clinical trials, which involves increased costs and time. For this reason, increasing attention is being paid to patients' emotions and motivations related to clinical trial participation. Their thorough understanding can be crucial not only to persuade patients to participate in clinical trials but also keep them in the trial.

This study aims to identify which expectations regarding clinical trials have the greatest influence on the decision to participate in them among a group of patients with rheumatic diseases.

Material and methods: Sixty-nine (50K/19M) patients with rheumatic diseases were included in the study. The mean age of the patients was 50.8 ± 12.9 years and the mean disease duration was 13.1 ± 9.3 years. Patients included in the study were asked to complete a questionnaire with questions about their reasons for participating in clinical trials, their emotions about it and their attitudes towards clinical trials.

Results: In the study group, the predominant reason for participating in a clinical trial was to receive positive information about the trial from a rheumatologist, with 45 (70%) respondents giving this answer. The second most common reason for enrolling in a clinical trial was the lack of improvement during standard treatment, with 32 (46%) respondents. The most frequently reported emotion associated with entering a clinical trial was hope — 53 (77%) of respondents.

Conclusions: People with rheumatic diseases who decide to participate in a clinical trial most often make this decision based on a conversation with their attending physician, with motivations and hopes associated with improved efficacy of a new therapy.

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KEY WORDS: clinical trials; rheumatoid arthritis; psoriatic arthritis; systemic lupus erythematosus; rheumatic diseases

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INTRODUCTION

Clinical trials are extremely important in the development of modern therapies. It would be difficult to talk about progress in modern medicine without them. Modern methodology has increased not only the efficacy of drugs used but also their safety. Today, we are already a far cry from the stories from the pages of J. Thorwald's books, which can seem downright abstract in this day and age [1].

Recruiting patients for clinical trials is not easy [2]. This is not only related to the controversy or concerns that medical experiments sometimes raise in society [3, 4]. The time patients have to spend to meet the requirements of trial protocols is also an important factor.

Therefore, a key factor in the recruitment process for a clinical trial is in fact the correct choice of patient. For this reason, researchers in the recruitment process should be aware that while the aim of a clinical trial is to assess the efficacy and safety of a new drug, it is impossible to do so without proper selection of a patient group.

The basis for inclusion and retention of patients in trials is to understand both their expectations and motivations. Only when the patients' expectations are met can they be expected to cope with the demands of an often very rigorous trial protocol that has a major impact on their daily life. This is particularly important when considering that the duration of the average clinical trial is many months and the trial protocol requires multiple diagnostic procedures. During such a period, the change in functioning can be cumbersome and discourage patients from a clinical trial if their expectations and benefits they see for themselves are not taken into account throughout the process.

The hopes and expectations of a clinical trial are very often linked to disease and its prognosis. In the absence of effective therapies, this can be an approach based on the principle that you have nothing to lose and something to gain.

Cancer patients are a specific group in this regard. In the subjective assessment, altruism is often the main reason for participating in clinical trials [5]. In contrast, the analysis by T.H. Truong found that, in fact, only a small percentage of cancer patients were motivated by altruistic motives when deciding to participate in the trial.

This means that it is difficult to identify patients' motivations for participating in a trial, and this may at the same time have a major impact on their participation or dropout.

However, understanding patients' motivations and expectations can definitely speed up the recruitment process. In their study, although conducted on a relatively small group of 42 patients, L. Locock et al. [6] obtained a very wide range of patient expectations of clinical trial participation. It should be noted that in addition to relatively obvious expectations such as better healthcare, patients also expected to have access to information about the latest research on their disease. The latter emphasises the importance of patient education — enabling patients to make more informed and rational choices that benefit them.

Catania et al. [7] performed a similar study, involving 102 patients. This study mainly aims to explore the cultural and emotional aspects that influence patients' decisions to participate in clinical trials.

Approximately one-third of survey respondents indicate that, when participating in a clinical trial, they are afraid of being treated as a "guinea pig" and doctors involved in the trial will give more weight to the scientific aspects of the trial than to looking after the interests of patients [7]. On the other hand, patients who decided to take part in a trial also hoped that they would have access to more effective treatment through that decision. Confidence in the doctor was also a big factor in deciding to participate in a trial.

Therefore, without knowing patients' expectations, without taking into account their concerns and without providing adequate education, it is difficult to expect rapid patient recruitment into a clinical trial.

This study aims to explore the expectations of patients with rheumatic diseases when deciding whether to participate in clinical trials.

MATERIAL AND METHODS

Sixty-nine (50K/19M) patients with rheumatic diseases were included in the study. The mean age of patients included in the study was 50.8 ± 12.9 years and the mean duration of disease was 13.1 ± 9.3 years. In the study group, 40 (32K/8M) patients had rheumatoid arthritis (RA), 17 (8K/9M) patients had psoriatic arthritis (PsA), 7 (6K/1M) patients had systemic lupus erythematosus (SLE) and 5 (4K/1M) patients had other rheumatic diseases.

The only inclusion criterion was the completion of at least one clinical trial at the time of completing the questionnaire on clinical trial participation and related expectations.

Patients included in the study came from four different clinical trial centres located in Bydgoszcz (2 centres), Toruń and Warsaw, and signed an informed patient consent form to participate in the proposed survey study.

The study was conducted in 2021.

RESULTS

Clinical trials are necessary to develop new therapies that provide patients with access to increasingly effective treatments. How-

Table 1. Demographic variables of individuals participating in the study

	Entire group (n = 69)
Average age [years] (± SD; median; min.; max.)	50 (± 12.9; 51; 23; 74)
BMI [kg/m^2] (± SD; median; min.; max.)	27 (± 5; 26; 20; 39)
Number of patients with BMI ≥ 25 [n] (%)	43 (62%)
Average duration of disease [years] (± SD; median; min.; max.)	13.1 (± 9.3; 10; 1; 40)

Source: authors' own study; BMI — body mass index; SD — standard deviation

Table 2. Clinical data: disease diagnosis

	Entire group (n = 69)
PsA [n] (%)	17 (25)
RA [n] (%)	40 (58)
SLE [n] (%)	7 (10)
Other* [n] (%)	5 (7)

Source: authors' own study; PsA — psoriatic arthritis; RA — rheumatoid arthritis; SLE — systemic lupus erythematosus; *Sjögren's syndrome, ankylosing spondylitis

ever, participation in clinical trials itself can sometimes raise ethical and patient motivation issues [8]. It is extremely important to have a doctor-patient conversation, providing accurate information about a clinical trial and making the patient aware of the benefits and possible risks of participating in it.

Such the most typical case of ethical and patient information issues is the first phase clinical trial for cancer patients in the terminal phase [8]. In many cases, patients are not fully aware of both the small therapeutic effect and the possibility of adverse events during the trial [8].

Patients with both cancer and rheumatic diseases are very often driven by altruism when deciding to participate in a clinical trial [8, 9]. In fact, such a decision is influenced both by a desire to help develop more effective therapies and by a better understanding of disease itself [9]. However, altruism cannot be considered to be the main factor driven by patients.

In fact, altruistic motives may — in a large group of patients — be the motivation for interest in clinical trials, although completing them may require a quite different kind of motivation. Participation in clinical trials strongly influences patients' routines [2]. Therefore, patient education about disease itself, therapies used or risks of clinical trial participation plays a very important role in convincing the patient to participate in the trial [10].

A conversation with the patient and explaining to them the benefits of participating in a clinical trial may in fact indicate quite different reasons and hopes for participating in a trial than the altruistic motives mentioned earlier.

In this study, patients answered a question about the reasons for participating in a clinical trial in the survey after the end of the clinical trial (Tab. 3). Two of the reasons mentioned can be considered prevalent.

The main reason that prompted patients to participate in a clinical trial was a conversation with their doctor and getting positive information from them about the trial. This was the answer given by as many as 70% of respondents. Therefore, it can be concluded

Table 3. Reasons for participating in a clinical trial

	Entire group (n = 69)
No improvement during standard treatment [n] (%)	32 (46)
Receiving positive information from patients' friends about treatment with biological and innovative therapies [n] (%)	17 (25)
Receiving positive information from a Primary Care Physician about treatment with biological and innovative therapies [n] (%)	8 (12)
Receiving positive information from a specialist in rheumatology about treatment with biological and innovative therapies [n] (%)	45 (70)
Receiving positive information from the press and/or the Internet about treatment with biological and innovative therapies [n] (%)	12 (17)
Receiving positive information from professional scientific opinions and reports about treatment with biological and innovative therapies [n] (%)	2 (3)
Lack of availability and accessibility of treatment with biological and innovative therapies under the NHF [n] (%)	22 (32)
Lack of possibility and availability of commercial treatment with biological and innovative therapies due to excessive financial costs [n] (%)	20 (29)
Long waiting time for the above treatment under the NHF [n] (%)	6 (9)
Other [n] (%)	5 (7)

Source: authors' own study; NHF — National Health Fund

Table 4. Attitude towards clinical trials before and after participation

	Before trial	After trial	p-value
Positive [n] (%)	54 (78)	66 (96)	0.010
Negative [n] (%)	1 (1)	0 (0)	
No opinion [n] (%)	14 (20)	3 (4)	

that doctors are perceived as the most reliable source of information.

The results of this study and those of other centres are consistent in this respect [9]. Patients interested in a clinical trial expect reliable information from a doctor in whom they have confidence. It is impossible to overestimate the role that the doctor has in educating the patient, providing information on possible methods of treatment, including clinical trials.

The second reason for wanting to participate in a clinical trial was the lack of improvement during treatment with standard available drugs — in this case, 46% of respondents indicated that reason. As this was a multiple-choice question, it should be noted that the other indicated answers included the lack of availability of such therapies under the National Health Fund (NHF) or the high cost of commercial treatment. Such answers were given by 32% and 29% of respondents, respectively.

These two aforementioned questions were designed with a view to assessing the availability of treatment with biologics in Poland. It is important to remember that access to this type of treatment is very limited in Poland compared to other European countries [11]. It can be assumed that in the absence of these two answers, a significantly higher proportion of patients would indicate a lack of improvement with standard available therapies. For these questions, the only logical explanation for seeking other therapies is the lack of efficacy of current drugs or side effects associated with their use.

The results presented in Table 3 show that altruistic motives, although very noble, may be the easiest answer from the patients' point of view. In reality, the reasons for participating in clinical trials may be quite different, much more mundane.

Table 5. Recommendations for family and friends

	Entire group (n = 69)
Yes [n] (%)	50 (72)
Rather yes [n] (%)	15 (22)
Rather no [n] (%)	2 (3)
No [n] (%)	0 (0)
No opinion [n] (%)	2 (3)

This is confirmed by the results of this study i.e., the most important role in convincing a patient to undergo a clinical trial is played by their doctor — confidence in the doctor, their knowledge and the lack of efficacy of current therapy. In terms of other reasons, which may also be related to the financial aspect mentioned, other studies indicated easier access to full diagnostics and laboratory tests [9].

The data presented in Table 4 show that patients participating in clinical trials have a positive attitude towards them, which is also influenced by the conversation with their doctor. Naturally, at this point, the ethical issue related to suggesting a patient participate in a clinical trial could be raised. In contrast, it should be noted that the proportion of patients who have a positive attitude towards clinical trials increases after their completion. In a way, this resolves possible concerns about the ethics of encouraging a patient to participate in a clinical trial. Since there is an increase in the proportion of patients who have a positive attitude towards trials, it can be concluded that participation in trials is beneficial for patients.

This is also confirmed by the results shown in Table 5. The majority of patients would recommend their family and friends to participate in a clinical trial if necessary.

The predominant emotion among those associated with clinical trial participation was hope (Tab. 6). New therapies, including

Table 6. Emotions associated with entering a clinical trial

	Entire group (n = 69)
Fear [n] (%)	5 (7)
Anxiety [n] (%)	5 (7)
Uncertainty [n] (%)	20 (29)
Concern [n] (%)	2 (3)
Surprise [n] (%)	0 (0)
Hope [n] (%)	53 (77)
Optimism [n] (%)	4 (6)
Joy [n] (%)	2 ()

Table 7. Reactions of family and friends to participation in a clinical trial

	Entire group (n = 69)
Positive [n] (%)	57 (83)
Negative [n] (%)	2 (3)
No opinion [n] (%)	10 (14)

those whose research results were presented at congresses or scientific conferences, very often find their way into the media, and can inspire hope that patients will improve if the new therapy is used [11].

Hope can be a very important emotion that influences both decision-making and patient motivation when adjusting to the rigour associated with clinical participation. On the other hand, it is difficult to imagine a patient who decides to participate in a clinical trial if they do not see the possibility of improving their health. For this reason, it seems that hope should be the predominant emotion in patients when they decide to participate in a clinical trial and thus change their current therapy.

Finally, it should be noted that patients who decided to take part in a clinical trial also had the support of their family and friends when making such a decision (Tab. 7). The support of family and friends can be just as important as a conversation with a doctor — in both situations, the person who considers taking part in clinical trials generally has confidence in these people.

CONCLUSIONS

Individuals who take part in a clinical trial usually make a decision based on:

A conversation with their doctor and they have support of family and friends;

A clinical trial is considered due to the lack of efficacy of the current therapy and the lack of access to biological therapies under the NHF;

The predominant feeling in people entering a clinical trial is the hope that their health status will improve with new therapy;

Communication with their doctor is a key factor in strengthening the patient's motivation to participate in clinical trials.

CONFLICT OF INTEREST

None declared.

CONFLICT OF INTEREST

The authors report no conflict of interest.

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