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# Survey study on volunteers participating in clinical phase trials of the national vaccine developed against COVID-19*

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## ABSTRACT

**Aims:** This study aimed to evaluate the sociodemographic characteristics, motivations for participation, and experiences of volunteers who took part in the phase 1 and phase 2 clinical trials of Turkovac, the first national COVID-19 vaccine developed in Turkiye.

**Methods:** A total of 230 volunteers participated in the study. Data on their demographics and perspectives on clinical research were collected using a structured questionnaire.

**Results:** The majority of the volunteers were male (76.1%) and residing in urban areas (87.8%). Of all participants, 91.7% were involved in the phase 2 trial and 8.3% in the phase 1 trial. Most volunteers reported that their motivation for participation was based on trust in the national vaccine. Furthermore, a significant part of the participants evaluated their clinical trial experience positively and expressed willingness to participate in future studies.

**Conclusion:** The findings of this study may provide valuable insights for the planning of future clinical trials and the development of effective strategies to increase volunteer participation.

**Keywords:** Survey, COVID-19, volunteer, clinical trials, Turkovac, national vaccine

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## INTRODUCTION

The COVID-19 pandemic emerged in December 2019 in Wuhan, China, and rapidly evolved into a global public health crisis. The World Health Organization (WHO) declared COVID-19 a pandemic on March 11, 2020; this process has profoundly affected societies, healthcare systems, and economies worldwide.[1] In the early stages of the pandemic, measures such as quarantine, social distancing, mask-wearing, and travel restrictions were implemented to control the spread of the disease, significantly impacting individuals' lifestyles and overall health. Vaccines, one of the most effective methods of protection against COVID-19, have played a key role in controlling the pandemic. Innovative vaccine technologies, particularly mRNA-based vaccines, enabled a rapid and effective response to the crisis. The World Health Organization has regarded COVID-19 vaccines as critical tools not only in ending the current pandemic but also in preparing for future outbreaks. In this context, increasing global access to vaccines and building public trust in vaccination have become central goals of global health policies.[2,3]

In this context, Turkovac, the first nationally developed COVID-19 vaccine in Turkiye, has marked a significant milestone in the management of the pandemic. Turkovac is an inactivated whole-virion SARS-CoV-2 vaccine. The vaccine was well tolerated after administration. The most common side effects were pain at the injection site and headache.[4] Phase 1 and phase 2 clinical trials of this vaccine, developed in collaboration between Erciyes University and the Turkish Health Institutes Directorate, were conducted at the Hakan Çetinsaya Center for Good Clinical Practice and Research of Erciyes University.[4] Turkovac has served as an example that highlights the importance of national vaccine development capacity not only in Turkiye but also globally.[5,6]

Although COVID-19 is no longer considered a global emergency, this study remains relevant and important in terms of understanding volunteers' perspectives on clinical trials related to the development of new vaccines. The development of national vaccines such as Turkovac plays a critical role in ensuring both national and global health security in the face of potential future outbreaks. Therefore, the aim of this study is to identify the sociodemographic characteristics of volunteers who participated in the Turkovac trials, understand their reasons for participation in clinical research, and evaluate their experiences throughout the process. The findings obtained may contribute to the planning of future clinical trials and to efforts aimed at increasing volunteer participation. Under pandemic conditions, the rapid completion of phase studies is crucial for public health. This study also crucial for demonstrating public orientation.

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## METHODS

### Study Volunteers and Questionnaire Design

This study was conducted with individuals who volunteered to participate in the phase 1 and phase 2 clinical trials of the Turkovac vaccine at the Hakan Çetinsaya Center for Good Clinical Practice at Erciyes University. The study was approved by the Erciyes University Non-interventional Clinical Researches Ethics Committee (Date: 03.03.2021, Decision No: 2021/149). All procedures were carried out in accordance with the ethical rules and the principles of the Declaration of Helsinki. Volunteers were informed that participation was entirely voluntary, and all participants signed an informed consent form prior to the administration of the questionnaire. Data were collected through face-to-face interviews between March 10 and April 10, 2021. A total of 230 volunteers were included in the study.

The questionnaire was designed to assess the demographic characteristics of the volunteers (gender, age, education level, place of residence, marital status, and occupation), their reasons for participating in vaccine trials, and any concerns experienced during the process. The questionnaire consisted of five-point Likert-Scale items, multiple-choice questions, closed-ended, and open-ended questions. The Likert-Scale items were rated as follows: 5: Strongly agree, 4: Agree, 3: Neutral, 2: Disagree, and 1: Strongly disagree. The questionnaire was developed by reviewing similar studies in the literature and was structured using scales and question sets from previous research, tailored to suit the purpose of this study.[7-11]

### Statistical Analysis

The data analyses of the collected data were performed using IBM SPSS Statistics version 22.0 (IBM Corp., Armonk, NY, USA). The normality of data distribution was assessed using the Kolmogorov-Smirnov test and box plot graphs. For the comparison of numerical variables, the independent samples t-test was used when the data were normally distributed, while the Mann-Whitney U test was applied for non-normally distributed data. The chi-square test ($X^2$) was used to compare categorical variables. A p-value of ≤0.05 was considered statistically significant.

## RESULTS

A total of 230 volunteers participated in this study, of whom 23.9% were female (n=55) and 76.1% were male (n=175). When the age distribution was examined, the largest group was in the 35-44 age range, accounting for 42.6% of the participants. Regarding educational status, 39.1% of the volunteers were university graduates (n=90), 28.7% were high school graduates (n=66), and 8.7% held a postgraduate degree (n=20). The vast majority of the volunteers were living in urban areas (87.8%, n=202). In terms of marital status, 65.2% were married (n=150) and 34.8% were single. The distribution of sociodemographic characteristics by phase 1 and phase 2 groups is presented in Table 1.

At the time of the survey, 91.7% of the volunteers (n=211) were part of the phase 2 vaccine trial group, while 8.3% (n=19) were in the phase 1 group.

**Table 1. Distribution of volunteers in phase 1 and phase 2 groups according to sociodemographic characteristics**

| | Total (n=230) | Phase 1 (n=19) | Phase 2 (n=211) | p-value |
|---|---|---|---|---|
| **Gender** | Female: 55 (23.9%) | 1 (5.3%) | 54 (25.6%) | 0.050 |
| | Male: 175 (76.1%) | 18 (94.7%) | 157 (74.4%) | |
| **Education** | Primary education: 39 (17%) | 4 (21.1%) | 35 (16.6%) | 0.632 |
| | Secondary education:15 (6.5%) | 1 (5.3%) | 14 (6.6%) | |
| | High school: 66 (28.7%) | 8 (42.1%) | 58 (27.5%) | |
| | University: 90 (39.1%) | 5 (26.3%) | 85 (40.3%) | |
| | Postgraduate: 20 (8.7%) | 1 (5.2%) | 19 (9.0%) | |
| **Marital status** | Married: 150 (65.2%) | 8 (42.1%) | 142 (67.3%) | 0.027 |
| | Single: 80 (34.8v) | 11 (57.9%) | 69 (32.7%) | |
| **Occupation** | Employed: 153 (66.5%) | 11 (57.9%) | 142 (67.3%) | 0.563 |
| | Unemployed 77 (33.5%) | 8 (42.1%) | 69 (32.7%) | |

Data are presented as number and percentage (%). n indicates the number of volunteers in each group. A p-value of ≤0.05 was considered statistically significant

When asked, "Are you worried about participating in the vaccine trial?", volunteers in the phase 1 group responded with an average score of 4.05±1.22, indicating "Strongly not worried." Similarly, the phase 2 group reported an average score of 4.3±0.99 (p=0.921), suggesting a similarly low level of concern. In both groups, the level of anxiety was found to be low. In response to the question "Has participating in this clinical trial changed your perspective on clinical research in a positive way?", the phase 1 group gave an average score of 4.42±0.60, while the phase 2 group responded with 4.26±0.81 (p=0.406), indicating a generally positive change in perception in both groups.

When the tendency to participate in another clinical trial in the future was evaluated, volunteers in the phase 1 group showed a higher inclination with an average score of 4.32±0.88, while those in the phase 2 group reported a lower tendency with a score of 3.88±0.88. This difference was statistically significant (p=0.041), indicating that the phase 1 group had a higher motivation to participate in future studies.

Responses to the question "Would you recommend participation in a clinical drug or vaccine trial to people around you?" were recorded as 4.11±0.80 in the phase 1 group and 4.27±0.66 in the phase 2 group (p=0.312). These results indicate that both groups were inclined to recommend participation in clinical research to others.

Responses to the question "Had you previously heard of terms such as phase 1 and phase 2 used in the development of drugs or vaccines?" were recorded as 4.05±1.17 in the phase 1 group and 3.79±1.09 in the phase 2 group. This difference was not statistically significant (p=0.323). These findings are presented in Table 2.

When volunteers were asked which vaccine they would prefer if there were equal access to all COVID-19 vaccines, 85.7% (n=197) stated that they would choose the national vaccine, Turkovac. This rate was 57.9% (n=11) in the phase 1 group and 88.2% (n=186) in the phase 2 group. The difference between the groups was statistically significant (p=0.002). Among other vaccine options, the mRNA-based Biontech/Pfizer

**Table 2. Volunteers' responses regarding their clinical research experience**

| | Phase 1 (n=19) | Phase 2 (n=211) | p-value |
|---|---|---|---|
| Are you worried about participating in the vaccine trial? | 4.05±1.22 | 4.03±0.99 | 0.921 |
| Has your perspective on clinical research changed in a positive way? | 4.42±0.60 | 4.26±0.81 | 0.406 |
| Would you participate in another clinical trial? | 4.32±0.88 | 3.88±0.88 | 0.041 |
| Would you recommend participating in clinical trials? | 4.11±0.80 | 4.27±0.66 | 0.312 |
| Had you heard of terms like "Phase 1" and "Phase 2"? | 4.05±1.17 | 3.79±1.09 | 0.323 |

All questions were evaluated using a 5-point Likert Scale (1: Strongly disagree, 5: Strongly agree). Data are presented as mean±standard deviation. n indicates the number of volunteers in each group. A p-value of ≤0.05 was considered statistically significant

vaccine was the second most preferred, chosen by 9.6% (n=22) of the volunteers. A detailed distribution of these findings is presented in Table 3.

When volunteers were asked, "What is your reason for participating in this clinical vaccine trial?", 42.1% (n=8) of the phase 1 group and 49.8% (n=105) of the phase 2 group stated that they participated because the vaccine was nationally produced. This difference between the groups was statistically significant (p=0.012). Another frequently reported reason for participation was the desire to contribute to science and to the development of a national vaccine. This reason was cited by 42.1% (n=8) of the phase 1 group and 45.0% (n=95) of the phase 2 group (Table 4).

When volunteers were asked whether they had previously participated in any clinical trial, 80.4% (n=179) stated that they had not taken part in any prior clinical research. In contrast, 19.6% (n=51) reported previous participation in a clinical trial.

Table 5 presents comparative data between volunteers with prior clinical trial experience and those participating for the first time.

## DISCUSSION

In this study, the sociodemographic characteristics, perspectives on clinical research, motivations for participation, and vaccine preferences of volunteers who participated in the phase 1 and phase 2 clinical trials of Turkovac, Turkiye's first national COVID-19 vaccine, were examined. The findings indicate that the majority of volunteers had a strong sense of trust in the Turkovac vaccine, and their motivation to participate in clinical trials was largely based on this trust. General trends of trust toward COVID-19 vaccines play a critical role in increasing vaccine acceptance rates.[11]

When examining the sociodemographic characteristics of the volunteers, it was observed that the participation rate of female volunteers was low. This finding suggests that participation in clinical research may be influenced not only by individual factors but also by social gender norms and interpersonal dynamics.[6,11] The literature suggests that women's participation rates in clinical research are generally lower than those of men, which may be attributed to a higher perceived risk among women regarding clinical trials. This situation highlights the need for developing specific strategies to ensure gender equality in research participation.[12,13] Additionally, the majority of volunteers participating in our study were between the ages of 32 and 44 and university graduates, suggesting that

**Table 3. Volunteers' vaccine preferences**

| | Total (n=230) | Phase 1 (n=19) | Phase 2 (n=211) | p-value |
|---|---|---|---|---|
| Inactivated virus vaccine; National vaccine – Turkovac | 197 (85.7%) | 11(57.9%) | 186 (88.2%) | 0.002 |
| MessengerRNA (mRNA) vaccine; Biontech/Pfizer | 22 (9.6%) | 6 (31.6%) | 16 (7.6%) | |
| Other options | 11 (4.7%) | 2 (10.5%) | 9 (4.2%) | |

Data are presented as number and percentage (%). n indicates the number of volunteers in each group. A p-value of ≤0.05 was considered statistically significant

**Table 4. Responses to the Question "What is your reason for participating in this clinical vaccine trial?"**

| | Total (n=230) | Phase 1 (n=19) | Phase 2 (n=211) | p-value |
|---|---|---|---|---|
| Because the vaccine is nationally produced | 113 (49.1%) | 8 (42.1%) | 105 (49.8%) | 0.012 |
| To contribute to science and the development of a national vaccine | 103 (44.8%) | 8 (42.1%) | 95 (45.0%) | |
| Other (financial reasons) | 4 (1.7%) | 3 (15.8%) | 1 (0.5%) | |

Data are presented as number and percentage (%). n indicates the number of volunteers in each group. A p-value of ≤0.05 was considered statistically significant

**Table 5. Responses based on previous participation in clinical trials**

| | Previously participated (n=45) | First-time participants (n=185) | p-value |
|---|---|---|---|
| Has your perspective on clinical research changed positively? | 4.29±0.78 | 4.27±0.80 | 0.889 |
| Would you participate in another clinical trial? | 4.22±0.76 | 3.84±0.90 | 0.010 |
| Would you recommend participation in clinical trials? | 4.27±0.75 | 4.25±0.66 | 0.911 |
| Have you heard of terms like phase 1 and phase 2? | 3.93±1.07 | 3.78±1.10 | 0.414 |

The questions were evaluated using a 5-point Likert Scale; data are presented as mean±standard deviation. n indicates the number of volunteers within the group. A p-value of ≤0.05 was considered statistically significant

this group is more willing to participate in clinical research. While a previous study found no age-related difference, participation in clinical trials decreased with increasing education level.[14] This suggests that pandemic conditions may have influenced individuals' willingness to participate in clinical trials, considering their age and education level. The fact that the vaccine was well tolerated and had few side effects in phase 1 may have also influenced the profile of people who preferred the vaccine in phase 2. On the other hand, unless clinical trial protocols mandate equal gender distribution among volunteers, it should be considered that researchers may prefer male participants, especially when taking into account the potential risk of pregnancy in female volunteers.

The findings of this study revealed that financial motivation, which is frequently emphasized in the literature, was not the primary reason for participation among the volunteers.[15-18] Instead, the majority of volunteers participated in the study not for financial gain, but due to their trust in the national vaccine and their desire to contribute to science. Although previous studies have suggested that volunteers are often motivated by financial incentives, this study highlights that trust in the national vaccine was the predominant factor for participation.[19] However, in clinical trials involving patient volunteers rather than healthy individuals, motivations such as the expectation of treatment or potential benefit from the investigational drug may become more prominent factors influencing participation.

The majority of volunteers stated that they would prefer Turkovac if there were equal access to all COVID-19 vaccines. This finding indicates that vaccine preference is not based solely on medical factors but is also influenced by social, cultural, and psychological elements. The literature emphasizes that individuals' attitudes toward vaccines are closely related to trust, identity, a sense of collective belonging, and support for national production. Especially during the pandemic, the spread of misinformation and anti-vaccine content on social media has been shown to significantly impact individual decision-making processes. Nevertheless, in this study, the high level of trust in the national vaccine appears to have combined with a sense of national solidarity, positively influencing vaccine acceptance. However, one of the limitations of this study is that the survey was conducted only with volunteers who participated in the Turkovac trial; thus, individuals who preferred other vaccines or who hold anti-vaccine views were not included.

Vaccine hesitancy cannot be explained solely by a lack of information; this attitude is also shaped by trust, values, and sociopolitical factors, and therefore, proposed solutions must also be multidimensional.[20] During the pandemic, uncertainties occasionally arose in society regarding the safety and efficacy of rapidly developed vaccines, which contributed to increased public distrust toward vaccination. Misinformation and anti-vaccine content, particularly those spread through social media, may have negatively influenced individual attitudes. Vaccine opposition has evolved into a global movement that is not limited to individual choices but is rooted in historical, sociopolitical, cultural, and even religious dynamics.[21] In this context, the high level of trust that the volunteers expressed toward Turkovac and their active participation in the process can be interpreted as indicators of both individual awareness and trust in nationally conducted clinical research. Indeed, a previous study also emphasized that gaining public trust plays a critical role in increasing demand for vaccination.[22] It is known that anti-vaccine campaigns are not limited to scientific arguments but are also supported by emotional and ideological content. Previous studies have reported that opposing narratives are based on various psychological factors such as distrust, fear, non-scientific beliefs, emphasis on personal autonomy, and conspiracy thinking.[23,24] In this study, the fact that the vast majority of volunteers actively participated in the process with trust in Turkovac suggests that the psychological resistance factors underlying anti-vaccine attitudes were limited in this sample and that the national vaccine gained meaningful public acceptance. In particular, the sense of trust provided by national production, the transparency of the scientific process, and clear and effective communication with volunteers may have played a role. In this regard, the development of Turkovac as a national vaccine is not only part of efforts to address the pandemic but also significant in that it represents the first locally developed vaccine to complete all stages-from laboratory to licensure-after a long period in which Turkiye lacked vaccine production capabilities. Overcoming the challenges encountered in the development of national vaccines holds great importance for sustaining public health and advancing vaccine development capacity in Turkiye.[6] In future vaccine development efforts and clinical trials, gaining public trust and enhancing volunteer motivation in areas such as scientific integrity, contribution to science, and service to humanity may help increase participation rates.[25]

## Limitations

One of the main strengths of this study is that it is the first to evaluate the motivations and experiences of volunteers who participated in the clinical trials of Turkovac, Turkiye's first national COVID-19 vaccine. However, the study has several limitations. The relatively small number of participants is primarily due to the study being conducted at a single center and under ongoing pandemic conditions, which prevented it from being planned as a large-scale, multicenter study. Therefore, the findings may not fully reflect the broader societal perspective. Additionally, the phase 1 and phase 2 groups were not equally represented, as the survey was initiated while phase 1 trials were still ongoing, resulting in a lower number of phase 1 participants. Most volunteers lived in urban areas, which limits the generalizability of the results to the general population. Furthermore, the low proportion of female participants led to gender imbalance. These limitations could be addressed in future research by including a larger and more demographically diverse sample. The phase 1 study, due to its small number of volunteers and its first application to humans, affected both the gender and education levels of participants. Moving to phase 2, it was observed that women and those with higher education levels were more willing to participate.

## CONCLUSION

As a result, this study reveals that volunteers' trust in a nationally produced vaccine played an important role in motivating their participation in clinical research. Moreover, since it is known that women and men use medications similarly under real-world conditions, special strategies should be developed to increase the participation of female volunteers in drug clinical trials, taking gender distribution into account.

## ETHICAL DECLARATIONS

### Ethics Committee Approval

The study was carried out with the permission of the Erciyes University Non-interventional Clinical Researches Ethics Committee (Date: 03.03.2021, Decision No: 2021/149).

### Informed Consent

Written consent was obtained from volunteers who participated in the study.

### Referee Evaluation Process

Externally peer-reviewed.

### Conflict of Interest Statement

The authors have no conflicts of interest to declare.

### Financial Disclosure

The authors declared that this study has received no financial support.

### Author Contributions

All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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