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RESEARCH

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What motivates SARS-CoV-2 vaccine trial participants? A pre- and post-participation survey study

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Abstract

Background Scientific advancement, including the testing and licensing of new drugs, relies heavily on clinical trials with healthy individuals. The motivations of clinical trial participants have been discussed intensively, as some worry that financial compensation may distract from the intrinsic risk of clinical research. Herein, we investigated the motivations and decisional factors influencing SARS-CoV-2 clinical trial participants. Moreover, since most surveys are administered after clinical trial participation, we were interested in whether the results were tainted by recall bias.

Methods This was a cross-sectional observational study. Participants were administered a survey on two occasions, once before and once after participation in a clinical trial. The primary outcomes were the motivations and decisional factors of SARS-CoV-2 vaccine trial participants and the difference between the surveys collected before and after clinical trial participation.

Results The survey response rate was 149/200 (75%). SARS-CoV-2 vaccine trial participants were mostly motivated by the desire to contribute to science and help others. Answers collected before and after the trial were not statistically different, indicating the absence of recall bias.

Conclusion The decision-making process of clinical trial participants is complex and multi-faceted. Previous studies have shown that clinical trial participants have mixed motivations but never to the extent reported in the current survey. Here, we present a theoretical framework that attempts to explain how different motivational factors may contribute to decision forming.

Background

Clinical trials, involving the testing of novel vaccines or drugs on humans, are a cornerstone of medical innovation. Any clinical research is tightly regulated, as laid down in the Nuremberg Code, the Declaration of Helsinki, and the Declaration of Belmont: key principles

include that participation should always be voluntary and the well-being and integrity of the participants should outweigh other considerations [1–3].

Clinical trials involving healthy individuals have received special scrutiny, because participants do not gain any benefits except for a financial compensation for the invested time and effort. The undue influence of payment has been questioned: is well-informed and voluntary participation possible if individuals are being remunerated [4–6]? Specifically, there are concerns that economically motivated participants may not sufficiently weigh the downsides of participation because they receive payment [7, 8]. However, it has been shown that financial reward is not the sole incentive for healthy

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volunteers, as they also hope to contribute to medical science or help others through their participation [9, 10].

The SARS-CoV-2 pandemic represented an exceptional situation, which put the healthcare system and society in general under high pressure. Clinical trials with healthy participants were pivotal for rolling out an effective vaccine. SARS-CoV-2 vaccine trials are an interesting case study, because they combined social benefit with the personal advantage of being vaccinated early. However, the motivations and decision-making process of SARS-CoV-2 vaccine trial participants have not been characterized yet.

Most surveys investigating motivational factors of participants are compiled at the end of a clinical trial. Answers collected in such a post hoc manner may be influenced by the experience of the trial itself or be tainted by recall bias. Questioning participants both before and after study completion can address these differences but has not been performed thus far.

This study employed a survey to investigate why individuals decided to participate in SARS-CoV-2-related clinical trials and how they experienced said trials, investigating their motivations both before and after study participation.

Methods

Participants

This study was approved by the medical ethical committee Leiden Den Haag Delft.

Healthy participants of SARS-CoV-2 vaccine trials, conducted at the Leiden University Medical Center (LUMC) in Leiden, The Netherlands, between 14-SEP-2020 and 02-JUN-2022 were invited to fill in the survey. Forty people participated in phase 2 of the Ad26.COV2.S SARS-COV-2 vaccine trial (NCT04535453), 93 in a post-licensure fractional dose study with the mRNA-1273 SARS-COV-2 vaccine comparing intramuscular and intradermal administration (EUCTR2021-000454-26-NL), and 16 in a post-licensure fractional dose study investigating the immunogenicity and safety of needle free delivery of the mRNA-1273 SARS-COV-2 vaccine (NCT05315362). All volunteers took part in a screening visit before participation in the original clinical trial, which consisted of signing of the informed consent forms after receiving study information including risks, possible side effects, and appointments and the opportunity to ask questions, followed by an anamnestic screening, physical examination, and laboratory tests.

There were no exclusion criteria for this survey study, and participation was voluntary.

Survey

The survey investigated factors influencing the motivation and decision-making process of clinical trial participants and was designed as previously described [10]. Briefly, survey items were chosen based on earlier research [11] and by discussion with researchers involved in the screening and recruitment of clinical trial participants. This survey has been implemented and evaluated in one other study [10] and can be found in the supplementary appendix.

Ten main domains were investigated: risk propensity, motivation, decision making, influence of others, experience of the clinical trial, severity of symptoms, and trust in the medical staff, informed consent, right to withdraw, and financial compensation.

The survey was anonymous and sent before start of the clinical trial on the inclusion day and on the day of the last trial visit. The electronic data capture system Castor was used to distribute the survey and record the responses. Participants who failed to fill in the survey were sent a maximum of two reminders.

Statistical analysis

The primary endpoint consisted of answers to the survey, expressed as a ranking of motivational factors and factors influencing the decision to participate. Secondary outcomes were comparison between pre- and post-survey answers and answers to multiple choice questions on expectations, experience, and opinion on ethical principles. Surveys that were filled in more than 1 day after start of the clinical trial and/or did not answer the primary endpoint were excluded from the analysis. Ordinal variables were ranked from highest to lowest. Frequencies were calculated for all items. Concerning the motivation, decision-making process, the importance of the screening interview, and the right to withdraw, we report the answers provided before clinical trial participation. In contrast, questions regarding the experience and evaluation of the participation and of the financial compensation were derived from the questionnaire administered after the clinical trial. To analyze the pre- and post-trial differences, ranked variables were dichotomized as follows: items marked as important or somewhat important were combined into one (overall important) and the same was done for items marked as a little important or not important (overall not important). The percentage of answers falling into the category "overall important" was then compared on the pre- and post-questionnaire by means of the McNemar test. The Bonferroni correction was used to adjust for multiple testing. All calculations were

Table 1 Baseline characteristics of the participants

Baseline table	N (%)
Number of volunteers	149
Sex	
Male	79 (53)
Female	70 (47)
Age	
18–24 years	85 (57)
25 to 30 years	35 (23.5)
1–64 years	12 (8.1)
65 +	17 (11.4)
Employment	
Student	80 (53.7)
Working	48 (32.2)
Other	21 (14.1)
Previously participated in research	
Yes	29 (19.5)
No	120 (80.5)
Employed in healthcare or healthcare related study	
Yes	30 (20.1)
No	119 (79.9)

carried out in IBM® SPSS® Statistics, version 25, and all graphs were made in GraphPad Prism, version 9.3.1.

Results

The survey response rate was 149/200 (75%). Most respondents were male (53%), students (53.7%) aged between 18 and 24 years old (57%). Moreover, 80.5% had not previously participated in clinical research, and 79.9% did not work in a healthcare related field (Table 1).

Motivation for participation and decision to participate

When asked before their participation about motivational factors, the majority of respondents answered that “contributing to science” was either very important (43%) or somewhat important (46.3%). This was closely followed by the desire to “help people in the Netherlands,” which was deemed very important by 35.8% and somewhat important by 46.6% of respondents. “Financial compensation” and “personal experience with the disease” were the two factors most often classified as only a little important (40.9% and 31.5%, respectively) and not important (14.1% and 58.4% respectively). 18.8% of participants scored financial compensation as “very important” (Fig. 1A).

In 26.2% of cases, “contributing to science” was the single most important motivational factor, closely followed by “financial compensation” with 20.1% of responses (Fig. 1B).

Respondents were asked to indicate which factors influenced their decision to participate in the clinical trial: “trust in the study team” was considered somewhat important by 40.5% and very important by 23% of respondents. In second place came the topic of the clinical trial, in this case “infectious diseases,” which was considered somewhat important by 35.1% and very important by 10.1% of respondents. “Chance of developing symptoms” and “opinion of others” were the two options that respondents weighted the least, being scored as somewhat important by 27.5% and 12.2% and very important by 8.7% and 2.7%, respectively (Fig. 1C).

Similarly, the two single most important factors influencing the decision to participate were “research about infectious diseases” (22.3%) and “trust in the study team” (18.9%) (Fig. 1D).

Before and after

The median time between administration pre- and post-trial questionnaires was 9 weeks. Generally, answers did not differ before and after the clinical trial (Table S1 and Fig. S1). Most importantly, motivational and decisional factors were largely unchanged in the pre- and post-surveys (Fig. 1E, F). Items that did show significant differences were the views on the screening interviews and the financial compensation. As far as the screening is concerned, fewer respondents remembered the appointments discussed during the initial interview after trial completion compared to before (65.3% pre-trials vs. 42.1% post-trial). Awareness of the clinical trial schedules, as discussed during the screening interview, is important for participant compliance during the trial. However, as a decision-making factor, the awareness of the schedule before the trial is most important. The perception of what participants considered the financial compensation to be intended for also changed to some degree, as fewer respondents saw it as a motivation for participation (56.2% pre-trial vs. 33.6% post-trial) and as a compensation for general expenses (52.1% pre-trial vs. 27.9% post-trial) after trial completion compared to before.

Reaction of others, screening, right to withdraw

Additional information regarding the participants’ experience was collected prior to the clinical trial.

Generally, respondents received positive reactions about their participation (92.9%) (Fig. S2A) and only few negative reactions (27.0%) (Fig. S2B). Others’ opinion did not influence their decision to participate (85.8%) (Fig. S2C).

The screening was deemed as somewhat important and very important by only 19% and 2% of respondents, respectively (Fig. S3A). In line with this, 83.6%

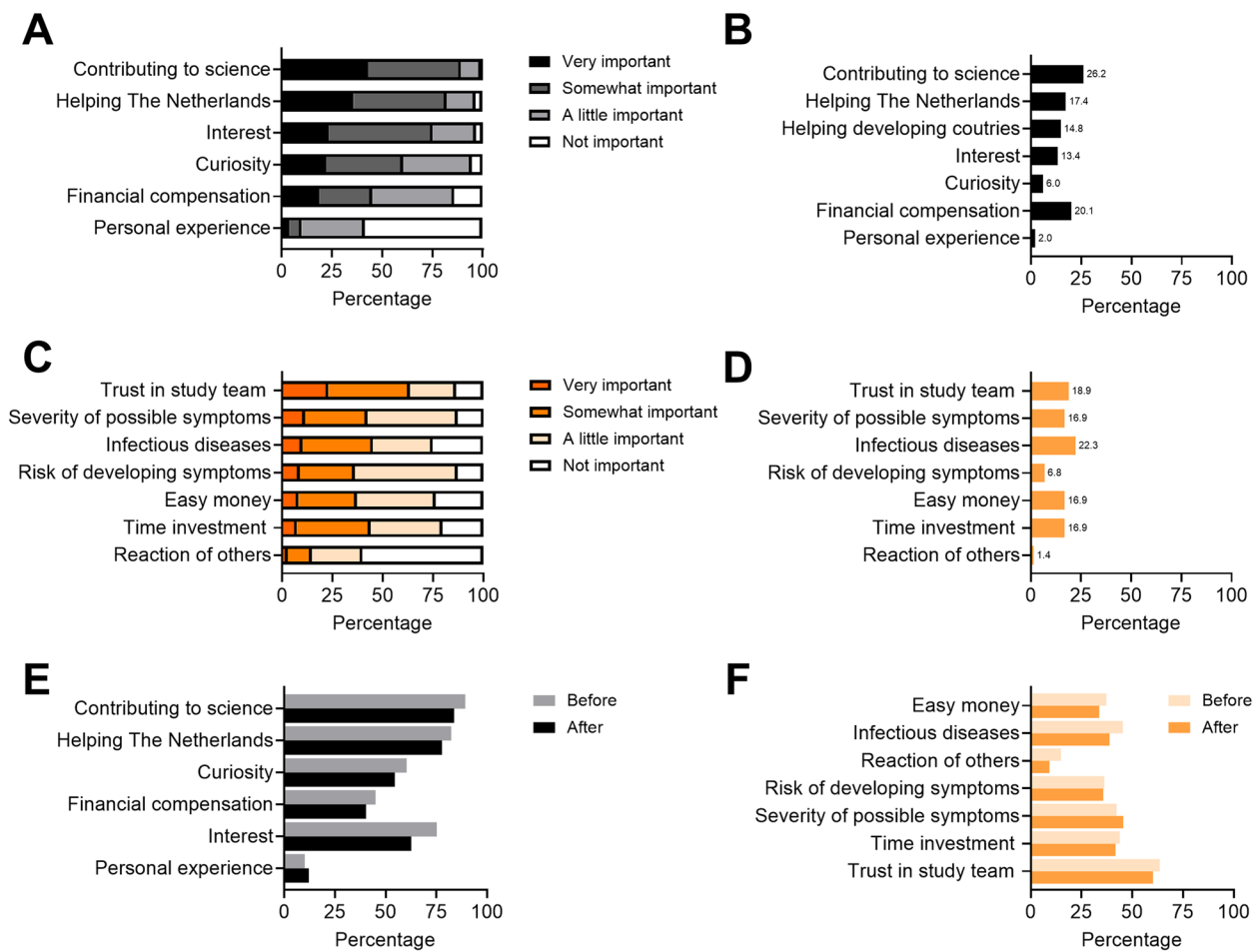


Fig. 1 Motivational factors and factors influencing the decision to participate. Ranking of motivational factors (A) and single most important motivational factor for participating in clinical trials (B). Ranking of decisional factors (C) and single most important decisional factor (D) for participating in clinical trials. Bar graphs depicting motivational (E) and decisional factors (F) to participate before and after the clinical trial

of respondents stated that the screening interview did not influence their opinion about the study, as they had already gathered enough information from the informed consent form they received beforehand (Fig. S3B). The most important thing respondents remembered from the screening were study related appointments (65.3%) (Fig. S2C). Most respondents agreed that the right to withdraw from the study at any time was either somewhat important (40.3%) or very important (32.6%) (Fig. S3D).

Evaluation of the experience and additional benefits

The evaluation of the experience was measured after completion of the clinical trial.

Receiving the vaccination was seen as positive by 49.0%, neutral by 34.3%, and scary by 16.7% of the respondents (Fig. 2A). The process of participating in the clinical trial was considered somewhat scary by only 1% of respondents; 52.1% and 18.8% found it somewhat or very interesting, and 5.2% and 1.0% rated

it as somewhat or very exciting, respectively (Fig. 2B). In general, respondents were proud that they had participated in the clinical trial (87.5%) and said they would participate again (89.6%) and even advise others to participate (92.7%). 78.1% of respondents admitted that they gained a personal benefit, other than financial reward, from their participation (Fig. 2C–F). When asked about the nature of such benefit (open questions), answers varied, but often focused on the health-related advantage of being vaccinated early. One participant wrote: “I was vaccinated, which was very nice. I also found it interesting to see how a clinical trial works and to learn about vaccines.” This answers exemplifies the dual motivations of clinical trial participants, who experienced the personal benefit of an early vaccination but also satisfied their scientific curiosity.

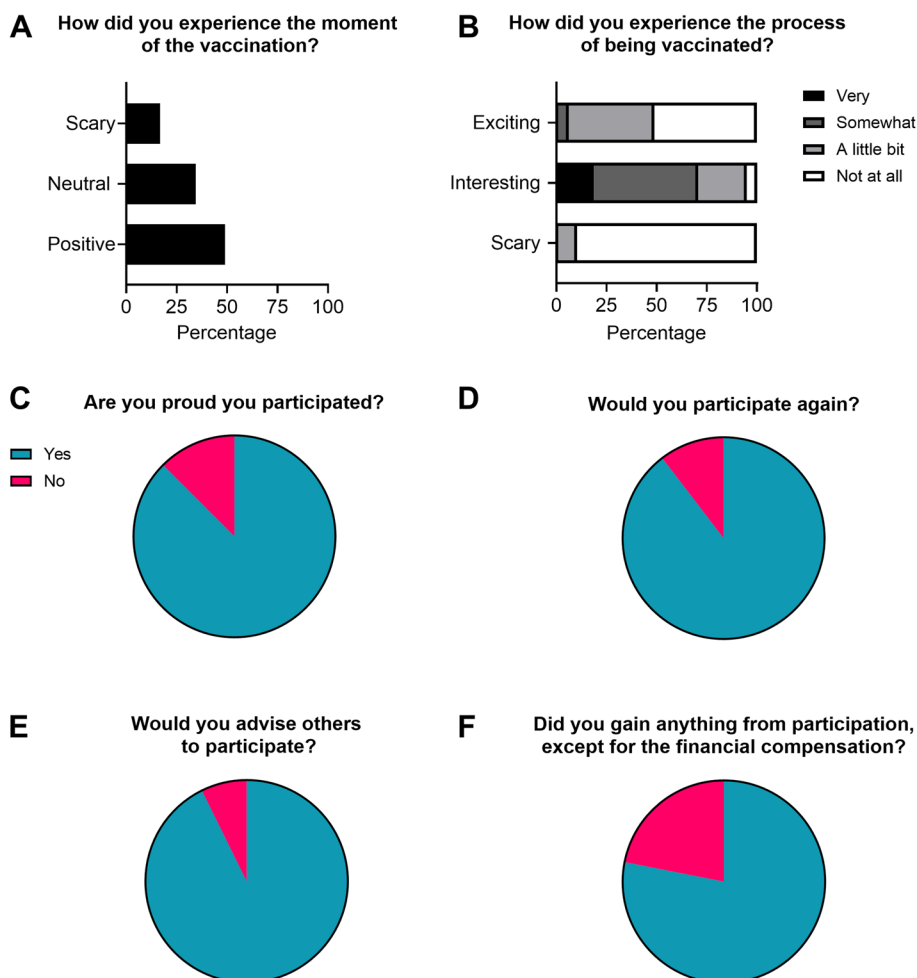


Fig. 2 Evaluation of the participation. Bar graphs indicating how participants experienced the moment (A) and the process of the vaccination (B). Pie charts indicating whether survey respondents were proud they participated (C), would participate again (D), would advise others to participate (E), and whether they gained anything from participation except for the financial compensation (F)

Financial compensation

Information about the financial compensation was derived from the post-trial questionnaire. As many as 44.7% of respondents would have taken part in the trial even without a financial compensation (Fig. 3A). 87.5% rated the financial compensation as good, 9.4% found that it was too low, and 3.1% too high (Fig. 3B). The majority of participants used the financial compensation for “daily expenses” and “other” purposes and saw it as a “motivation for participation” (33.6%) or a “compensation for risk” (27.9%) (Fig. 3C, D).

Discussion

In this study, we described the characteristics and the motivational and decisional factors of SARS-CoV-2 clinical trial participants in the Netherlands. We also investigated whether answers were reported differently before and after participation.

We found that the majority of respondents were motivated by the desire to contribute to science or to helping the Netherlands. Financial compensation was classified as very or somewhat important by less than half of the respondents in a ranking of motivational factors and was the single most important motivational factor for only 20% of participants [10]. When deciding to take part in a trial, participants made a balanced decision involving trust in the study team, possible burdens, and the importance of the research question. Reported motivational and decisional factors did not change after participation.

These results highlight the extraordinary conditions of the SARS-COV-2 pandemic. Mixed motivations have been reported in previous studies as well but less pronounced than in the current instance [10, 12]. While competence and friendliness of the study team were identified as important decisional factors in the past

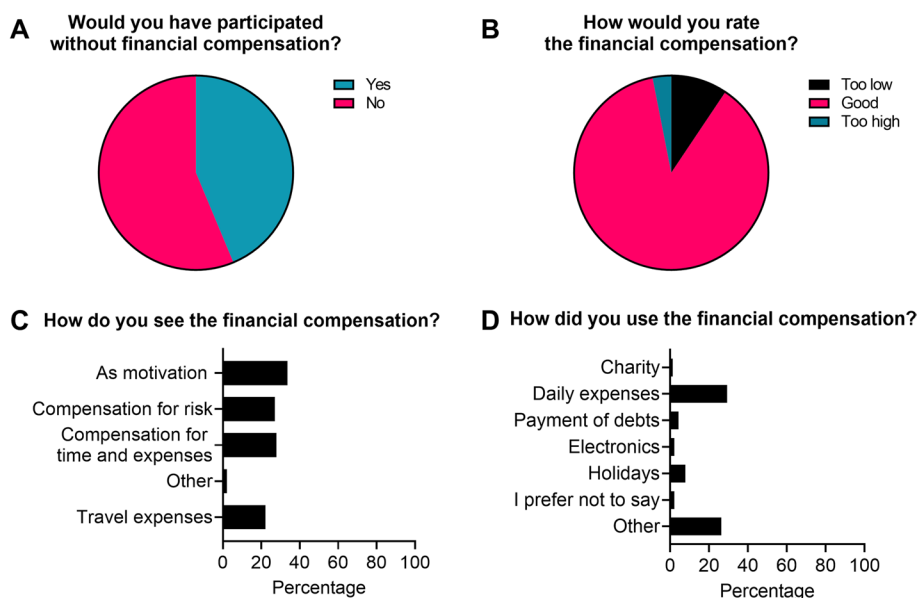


Fig. 3 Financial compensation. Pie charts indicating how many respondents would have participated without financial compensation (A) and evaluation of the financial compensation (B). Bar graphs indicating what the respondents thought the financial compensation was intended for by the researchers (C) and its actual use by the respondents (D)

[11], financial reward is often indicated as the main motivation for participating [11, 12]. In this regard, it is interesting that as many as 44.7% of our survey respondents would have participated in the clinical trial even without a financial compensation.

The question then arises of whether SARS-CoV-2 study participants fall into a special category of medical volunteers, with distinct and mostly selfless motivations and, if so, what accounts for these characteristics.

We postulate that the underlying motivations of medical volunteers participating in any clinical trial are fundamentally the same. However, external circumstances may affect how motivational factors are weighted, amounting to a different decisional outcome depending on the situation. According to our hypothesis, the decision to participate in a clinical trial is compounded by three elements: the reward of participating, the cost of inaction, and the risk of suffering negative consequences from participation. If the sum of the rewards and the costs of inaction are higher than the risks, the decision will be in favor of participation, against it otherwise (Fig. 4).

The rewards of participating in a SARS-CoV-2 vaccination trial were high: besides the financial compensation, medical volunteers potentially derived a personal advantage from their participation, as it allowed them to be vaccinated before the rest of the population. Of course, it should be noted here that while benefit from participation in clinical trials may be an added bonus, it is never

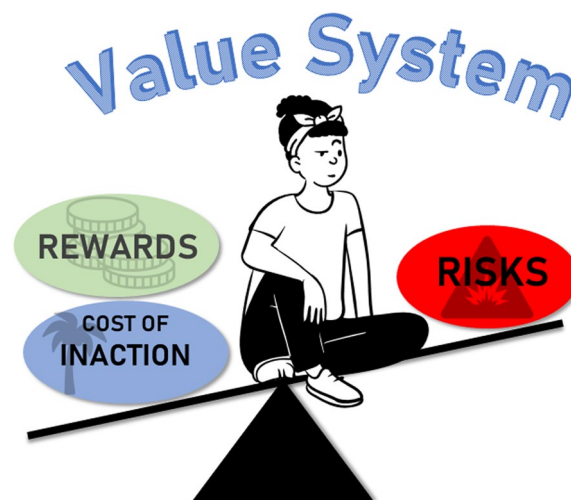


Fig. 4 Theoretical model of the decision-making process of medical volunteers. The sum of the rewards and the cost of inaction must exceed the risks for a healthy individuals to decide to take part in a clinical trial

guaranteed and one should be careful not to introduce therapeutic misconceptions about the scope of any type of clinical research.

Secondly, the cost of inaction was high, as the pandemic was a very tangible threat that directly affected the lives of clinical trial participants. In line with this, the proximity of the threat also accounts for its perceived danger and

urgency. This concept has been most famously described by Peter Singer's drowning child thought experiment: humans feel more compelled to help when suffering is close by than when it is far removed [13, 14].

It is not surprising then that the volunteer-led initiative 1DaySooner, whose members advocate for participation in high-risk, high-gain challenge studies [15], was founded during the pandemic. 1DaySooner continues to exist even now, yet it was the immediacy of the threat that brought it to life.

Any altruistic motivations, that is, the desire to help others independently of one's own gains [16], may also be considered an extension of this second postulate. In other words, the risk of inaction is determined by how heavily one weighs the lack of a cure for the disease under study. However, altruism remains a controversial philosophical and sociological concept and some have argued it to be a form of disguised egoism [17–19].

Finally, another factor that influences an individual's decision to partake in a clinical trial is the perceived risk. Most SARS-CoV-2 vaccine trial participants described in the current study were not scared of being vaccinated and judged the risk of the study to be absent or moderate. It is doubtful whether someone convinced that vaccinations would harm them would have participated in any SARS-CoV-2 trial, no matter what the benefits.

It should be noted that the evaluation of each of the above-mentioned factors, namely the rewards, the cost of inaction, and the risks of participation, is subjective and highly dependent on personal beliefs and circumstances, which may be referred to as value system.

Comparing SARS-CoV-2 vaccination trials to the conceptual framework of other, "regular", clinical trials shows how situational circumstances may affect the outcome of the decision-making equation.

Healthy individuals usually have little to no personal incentive for participating in clinical trials. The chances that they will directly benefit from the tested drugs is minimal and remote, making financial compensation the main reward. The risk of inaction is usually low for healthy individuals, as their lives are not directly affected by the outcome of the clinical trial. Conversely, the risk of participation is relatively high for healthy medical volunteers: if anything, they might be better off not taking part and avoiding the risk of side-effects.

In this model, financial compensation may be the only factor weighing against the risks and burdens of participation. We postulate that economic reward should not be considered an undue influence on participants, but rather a component of a weighted decision to do or do not take part in clinical research. While the absence of truly altruistic motivations may appear callous to some, it would be inappropriate to utter judgement.

The framework presented herein is not meant as a moral guide but rather as a tool to understand human behavior.

The second research question concerned the recall bias of surveys administered after clinical trial participation: little change in answers was observed comparing the pre- and post-participation surveys. The participants' judgement is unaffected by time and/or by the experience of the trial itself, further highlighting the consistency of our results over time.

The evaluation of the most important aspects of a clinical trial, are, among others, dependent on the education and information provided by the research team during the informed consent briefing. Providing extensive and adequate informed consent is of great importance to aid the potential participant in their decision to partake in the trial. Our study shows that participants do weigh the provided information carefully and that the outlined expectations corresponded to reality, emphasizing the importance of the informed consent procedure.

Respondents were participants of a number of different types of trials, ranging from phase 2 vaccine studies to post-licensure fractional dose immunization studies. This might induce response bias, if answers differ depending on trial. Another concern is that self-reporting respondents may not be completely honest [20]. However, the surveys were anonymous, thereby alleviating the pressure to answering in a socially desirable way.

This study shows that the SARS-COV-2 pandemic induced clinical trial participants to behave differently than previously observed [10, 21, 22]. We propose a theoretical framework to explain the decision-making process that leads healthy individuals to participate in clinical trials. This framework shows that the underlying motivations of medical volunteers participating in any clinical trial are fundamentally the same, but that context determines actual behavior. The framework can be a starting point for further research whether medical volunteers can identify with it.

Moreover, we show that recall bias of questionnaires administered after a clinical trial is negligible and that the answers to such questionnaires may be considered reliable. Overall, the opinions and impressions of medical volunteers are not easily swayed by time and the experience of the trial itself.

Our results highlight that the agency of medical volunteers who freely decide to participate in a clinical trial should be recognized. Especially in high-risk, high-gain situations, medical volunteers may consider a variety of factors when deciding to participate in a clinical trial. Just as it is important that individuals are not coerced into partaking in research against their will, their informed decision to do so, should also be honored.

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s13063-024-08582-z>.

Supplementary Material 1. Table S1. Fig. S1: Answers before and after participation in the clinical trial. Fig. S2: Reaction of others. Pie charts indicating how many participants received a positive (A) or negative (B) reaction about their decision to participate and whether the influence of others influenced their decision to participate (C). Fig. S3: Screening. Bar graphs indicating how important the screening was (A), the most important information participants remembered from the screening (B), whether the screening changed their opinion about the trial they planned to participate in (C) and the importance of the right to withdraw (D).

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Authors' contributions

MA Hoogerwerf and M Roestenberg designed the study and provided guidance and advice writing the manuscript, MC de Vries gave extensive conceptual feedback, and OAC Lamers analyzed the data and wrote the text. All authors take responsibility for the data and the corresponding author confirms that all co-authors meet the authorship criteria and that no others meeting the criteria have been omitted.

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Data availability

The datasets analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

This study was approved by the medical ethical committee Leiden Den Haag Delft.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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