of patients with Covid-19 (confirmed or unconfirmed), this group of patients represent a large number. However, these patients represent a 'blind spot' with regard to management, detection and priority compared to the more severely ill patients.[17] Our study highlights the need for psychosocial rehabilitation of this group of patients. Our study also underlines the importance of undertaking more systematic studies of stigma and the economic and health consequences of Covid-19 across the spectrum of symptomatic severity.

Conflicts of interest. None declared

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Evaluation of satisfaction and reasons for participation in a Covid-19 vaccine clinical trial: A single-centre, observational study

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ABSTRACT

Background. In May 2020, WHO recognized the role of extensive immunization for interrupting the transmission of the SARS-CoV-2 virus. The development of such vaccines in clinical trials relies upon participants who are expected to be vested in the research process. Assessment of participant factors such as motivation and satisfaction are hence important to gauge perspective and ensure successful conduct and completion of these trials.

Methods. We administered a validated three-domain questionnaire to and documented the binary categorical responses (yes/no) of participants (after informed consent) who had taken both doses of COVOVAX™ in a phase 3 trial at our institute. Association of the dependent variables (participant responses) with the independent variables (participant demographics and socioeconomic strata) was computed using Chi-square test at 5% significance. In case of a significant association, Bonferroni post-hoc test was applied for multiple comparisons.

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Results. Of the 78 participants who were administered the questionnaire, two-thirds were highly satisfied with their experience at our site. Gaining access to a new vaccine was a primary motivation overall (74%) and also in graduates ($p=0.03$) and middle-class population ($p=0.002$), whereas the lower-middle class population ($p<0.0001$) and those educated till secondary school ($p=0.003$) took part due to the long wait for government-approved vaccines.

Conclusion. Participants in a Covid-19 vaccine trial at Mumbai were largely satisfied with the care given to them though altruism did not feature as a primary reason for participation.

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INTRODUCTION

The development of a safe and effective vaccine has been a challenge for scientists since the start of the Covid-19 pandemic.[1] Till 3 June 2022, a total of 38 Covid-19 vaccines have got approval at least in one country while 205 vaccine candidates are available worldwide for which 715 clinical trials are ongoing.[2] Clinical trials have been the mainstay of vaccine development in this ongoing pandemic. The conduct of successful, high-quality trials with rapidity in a pandemic relies on enrolling and retaining healthy participants who are vested in and understand and trust the research process.[3] Their motivation and satisfaction is a key factor in the successful completion of these studies.

There could be several reasons as to why otherwise healthy people choose to participate in clinical trials, especially in a pandemic. An assessment of these factors will give us an insight into the reasons and help plan future trials..[4] We aimed to assess the satisfaction and factors that motivated participants to take part in a Covid-19 vaccine trial conducted at a tertiary referral hospital that houses a clinical research department.

METHODS

Ethics

The study was approved by the institutional ethics committee (EC-OA/184/2021). As per the directive of the institutional ethics committee, participants' consent was obtained verbally and this was audio recorded over the telephone. The trial was registered prospectively with the Clinical Trials Registry of India (CTRI/2022/03/040969).

Eligibility criteria

Participants who had consented for a Covid-19 vaccine trial at our centre (CTRI/2021/02/031554, two-dose vaccine) formed the study sample. All participants who provided consent were included in the study. Those who withdrew consent and those who did not complete the study (a total of 6 study visits) for any reason were also included. Those who had not taken both doses of the vaccine were excluded.

Questionnaire development

We developed our own questionnaire for the study. It consisted of 15 questions divided into three domains with binary (yes/no) responses. This questionnaire was based on the personal experiences with any vaccine trial in the past by the senior author and the general reasons enunciated by participants in these studies. The domains were: (i) satisfaction from participation in the study; (ii) factors that motivated them to participate; and (iii) motivation for participation in future vaccine trials. The satisfaction domain had 8 questions with yes or no responses. The minimum possible score was 0 and maximum 8. The domain that assessed factors that motivated the participant to volunteer for the Covid vaccine trial had 5 factors and more than one response could be checked. The final domain had 2 questions with binary responses (Table I).

TABLE I. Questions asked under various domains of the questionnaire administered to the participants

Domain 1: Participant satisfaction
1. Facility was conducive for the study
2. Research staff was knowledgeable and explained the procedures
3. Was fully informed of risks and benefits for participation
4. Understood my participation is voluntary and can withdraw at any time
5. Research staff was approachable for my questions and concerns
6. Sufficient time was spent with me
7. Received reminders about upcoming visits
8. Overall experience was positive
Domain 2: Motivation factors for participation
1. To gain access to the new Covid vaccine
2. To gain access to the Covid vaccine due to the long wait for government-approved vaccines
3. To help society (altruism)
4. For financial gains
5. To get a free routine health check-up done (RTPCR and Covid antibody check-up) which otherwise would cost me money
Domain 3: Motivation for future participation
1. Would like to participate in any further research at the trial centre
2. Would recommend others to participate in such research studies

Questionnaire validation

This was done using the Kuder–Richardson 21 formula[5] which is a specialized form of Cronbach alpha measure for reliability of a test with binary variables. The scores for KR-21 range from 0 to 1, where 0 is no reliability and 1 is perfect reliability. The closer the score is to 1, the more reliable the test. A questionnaire score of over 0.5 is usually considered reasonable. The questionnaire was administered to 30 people whose replies were then transcribed in an Excel sheet and found to have a score of 0.66.

Questionnaire administration

Initially, we contacted the participants telephonically. Subsequently, the study was explained in detail to them in the language comfortable to them. They were given the choice of declining consent. After taking and recording their verbal consent, questions from all the domains in the questionnaire were read out to the participants slowly one by one and their replies were noted.

Outcome measures

We recorded identifiers such as age and gender, education and employment status. Using the per capita family income of the participants, they were classified into various socioeconomic classes using the BG Prasad scale[6,7] (Table II). The BG Prasad scale, first introduced in 1961 is the one of the most widely used scales to classify the socioeconomic status based on the family's per capita income.[8] Over the years, it has been modified to incorporate the dynamic effect of the consumer price index on the per capita income leading us to use this scale for

TABLE II. Socioeconomic classes as per the per capita income defined by BG Prasad scale (updated January 2022)

Socioeconomic class		Per capita income/month (₹)
Class I	Upper class	8224 and above
Class II	Upper-middle class	4112–8223
Class III	Middle class	4111–2467
Class IV	Lower-middle class	1234–2466
Class V	Lower class	1233 and below

assessment of social class. Other outcome measures included (i) proportion of participant satisfaction scores after volunteering; (ii) proportion of participant responses to specific factors that motivated them to participate; (iii) proportion of participant responses to saying yes to future studies; and (iv) association of dependent variables (satisfaction, motivation and future motivation) with the independent variables (age, gender, employment, education status, socioeconomic status).

Statistical analysis plan (SAP)

Both descriptive and inferential statistics were applied to the data. Categorical data such as age, gender, education, employment status and socioeconomic class were expressed as proportions. Participant responses for each factor (satisfaction score, motivation reason, future motivation) were also expressed as proportions. Association of the dependent variables (participant responses) with the independent variables (demographics and socioeconomic strata) was computed using Chi-square test. If and when a significant association was found in Chi-square test, Bonferroni post-hoc test was applied for multiple comparisons. All statistical tests were done using SPSS, Version 25 (IBM Corp., Armonk, New York, USA, 2017) at 5% significance.

RESULTS

Demographics

A total of 97 participants had completed both doses of the vaccine and were contacted telephonically. Of these, 78 (80%) consented to participate in the study. There were 72 (92%) men and 6 (8%) women. Of these, 2 participants had completed only two visits of the study. Forty-six per cent of the participants belonged to the age group of 18–35 years. Eighty-three per cent were either graduates or were educated till secondary school; 68% of them were also employed (Tabe III).

TABLE III. Overall demographic profile of the participants

Variable (*n*=78)		*n* (%)
Age group	18–35 years (young adults)	36 (46)
	36–55 years (middle age)	33 (42)
	56 years and older (older)	9 (12)
Gender	Men	72 (92)
	Women	6 (8)
Education	Primary school (till class 8)	13 (17)
	Secondary school (till class 12)	34 (43)
	Graduate and above	31 (40)
Employment status	Employed	53 (68)
	Unemployed	25 (32)
Socioeconomic class	Class I (upper class)	15 (19)
	Class II (upper-middle class)	26 (33)
	Class III (middle class)	25 (32)
	Class IV (lower-middle class)	7 (9)
	Class V (lower class)	5 (6)

BG Prasad scale

A total of 15/78 (19%) and 26/78 (33%) of the participants in the study were classified as upper class and upper-middle class, respectively, 25/78 (32%) were classified as middle class whereas 7/78 (9%) were lower-middle class and 5/78 (6%) lower class. The details of the demographic profile of the participants are given in Table III.

Participant responses to the questionnaire

Domain 1—Satisfaction. A total of 47/78 (60%) participants had a 100% satisfaction score of 8/8, while 21/78 (27%) of them had a score of 7/8 and 10/78 (13%) had a score of 6/8. No participant scored less than 6 on the questionnaire.

Domain 2—Motivation for participation. We found that gaining access to a new Covid vaccine (74%) was the primary reason for participation in the trial, while 31/78 (40%) took part to get a free health check-up done. Approximately one-third 29/78 (37%) took part in the study as the vaccine was free and for their age group and payment in the the private sector was not possible for them (at the time of this study, vaccines were not provided free by the government for this age group). Another one-third 28/78 (36%) cited altruism as their reason for participation. A quarter, 21/78 (27%) had participated to avail travel reimbursements given as part of the study.

Domain 3—Motivation for future participation. Almost all the participants 76/78 (97%) were motivated to take part in any further research at the trial site and 69/78 (89%) were also ready to recommend others for such trials.

Impact of participant variables on their responses

We did not find any association of the independent variables of age group, gender and employment status with any of the dependent variables ($p>0.05$).

Educational level

The satisfaction score for the trial site experience was significantly higher among those who were either graduates or had a degree higher than graduation (84% had a score of 8/8) ($p<0.001$) while those educated until primary school or lower had much lower satisfaction scores (62% had a score of 6/8) ($p<0.00001$).

We found that graduates and those with higher than a graduate degree were significantly more motivated to participate in the trial to gain access to a new Covid vaccine compared to those with lower education ($p=0.03$). Similarly, graduates were altruistic compared to the rest though the association did not reach statistical significance. Those who were educated till secondary school had a significantly higher motivation for taking the trial vaccine due to the long wait for government-approved vaccines compared to those who were graduates or above ($p=0.003$).

Participants with education till primary school cited a significantly greater motivation to participate in any future trials than the others ($p<0.001$).

Socioeconomic status

The participants categorized as upper class gave a significantly greater satisfaction score to their trial experience as per their responses to the questionnaire compared to the other socioeconomic classes ($p=0.004$) (Fig. 1).

The middle-class population was significantly more motivated to participate in the trial to gain access to a newer

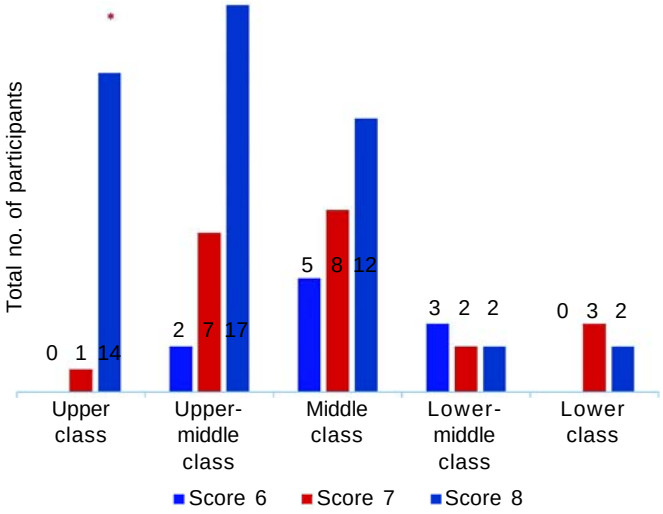

FIG 1. Satisfaction scores of various socioeconomic groups

vaccine for Covid (p=0.002) while the participants classified under the lower-middle class category had a significantly higher motivation for taking the trial vaccine due to the long wait for government-approved vaccines (p<0.0001). Though all the participants under the lower-class category were motivated to participate in the vaccine trial to get a health check-up done compared to the others, but the association was not found to be statistically significant (p>0.05).

DISCUSSION

We assessed satisfaction and reasons for motivation in 78 healthy participants (92% were men) who took part in a Covid-19 vaccine trial at our institute. We found that two-thirds of participants were satisfied with their treatment and care given to them as part of the trial. Gaining access to a Covid-19 vaccine, free medical check-ups were the primary reasons for participation followed by altruism. Graduates and those from the upper socioeconomic strata had better satisfaction scores compared to non-graduates and those from other socioeconomic strata.

From the original clinical trial, only those who consented to participate in the present study were included and the proportion of men was high at 92%. This was also seen in the regulatory trial where 92% of the participants were men. As a negative pregnancy test was a selection criteria in the original trial along with the use of contraception till the 36-day visit, this may have led to the exclusion of women participants. This also reflects that women as a group have been historically largely unrepresented in clinical trials.[9] Over the years, with regulatory backing, there has been an increase in representation of women in clinical trials.[10] Steinberg *et al*. evaluated not just the representation but also representation relative to the disease burden in a developed country and found women to be underrepresented in paediatric and oncology trials.[11] As Covid-19 is a disease that cuts across all ages, this under-representation in a metropolitan city like Mumbai is worrisome. Potential reasons could be lack of autonomy as shown by us in an earlier study by Figer *et al*., and the worry about risk to the foetus precluding their participation.[12] Abdelhafiz *et al*., in their questionnaire-based study on 576 healthy participants in Egypt, also found that women were more likely not to take part in Covid-19 trials compared to men.[13]

The regulatory trial was done for a new Covid-19 vaccine and most healthy persons who consented to participate were either in age range for young adults (18–35 years) or middle age (36–55 years). We can only surmise about the reasons for participation of very few older participants. These could be frailty, comorbidities, need for travel to the hospital for follow-up, which would have required a caregiver and therefore posed challenges regarding compliance with the trial protocol.[14]

A total of 13% of participants were not entirely satisfied with the trial. The major reason of dissatisfaction was that sufficient time was not spent with them by the trial team. This may have been due to the stringent timelines of recruitment at our site and a small trial team. Bassi *et al*. made a similar observation that research studies in India are challenging due to reasons such as limited workforce, and scarce facilities leading to operational difficulties.[15] During Covid-19, this would have been magnified due to the pressure on the workforce that was not just working for the trial but was also involved in care for Covid-19 patients. More time may be given to individual participants in future studies as a greater investment in time leads to a better understanding in research participants.[16]

Almost three-fourths of the study population stated that they were motivated to participate in the trial to gain access to a new Covid vaccine. The Covid-19 pandemic has put tremendous pressure on researchers, regulators as well as policy-makers to bring new vaccines into the market to make it available for the general public in a timely manner.[17] At the time this trial was done, the vaccines available in India were Oxford-Astra Zeneca vaccine locally referred to as Covishield™, Bharat Biotech-ICMR (Indian Council of Medical Research) indigenous vaccine named Covaxin™ and the imported Russian Sputnik V™ vaccine.[18] Despite this, there was hesitancy in certain sections of the population towards these vaccines and there was a quest for newer remedies. In a study by Danabal *et al*. on 596 persons in southern India, the primary reason for vaccine hesitancy was lack of sufficient credible information.[19] In contrast to our results, in northern India, monetary gains were found to be a major reason for participation.[20] It is difficult to assess the reason for motivation; we can only hypothesize about it. Contracting serious/severe disease is another possibility for which the participants wanted access to the vaccine.

We found that those with higher education were more satisfied. Other studies have also shown that participants with higher education understand research better.[21–24] Understanding the trial process is essentially via the informed consent form. The lengthier the form, the more tenuous it is for the participant who is less educated. Grant *et al*., in their review, stated that the longer the informed consent document is, the less likely it is for people to read and understand it fully.[25] The consent form in our clinical trial was nine pages long which could have been a deterrent for those who were less educated.

The vaccine rollout in India began from 16 January 2021, initially only in the public sector for the healthcare workers and for those above 60 years of age, whereas all individuals above 18 years of age were made eligible to receive them only from 1 May 2021,[26] leading to a long wait for the vaccines to be made available from the government sector. This group was likely to have said yes to the vaccination trial to gain access and not being able to pay for the vaccine in the private sector.

Our study is restricted to a largely male population at a single centre and of a single Covid-19 vaccine trial and needs to be viewed in that perspective. Also, the questionnaire developed

by us may not have captured all facets of satisfaction and motivation. The use of telephone as a tool for communication was an inherent limitation as it was impersonal without direct contact. This could have impacted responses given by the participants and also the lack of control of the investigator over the environment of the participant with potential distracters.[27]

In summary, 78 participants in a Covid-19 vaccine trial at Mumbai were largely satisfied with the care given to them though altruism did not feature as a primary reason for participation.

Conflicts of interest. None declared

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