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Original Article

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# The impact of the COVID-19 pandemic on recruitment in a multi-center clinical trial of rotator cuff tears

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## Abstract

**Objectives:** This study aims to examine screening and accrual data from a unique multi-center clinical trial for rotator cuff tears before and after the trial was paused due to the novel coronavirus disease 2019 (COVID-19) pandemic.

**Patients and methods:** Between March 2018 and December 2023, the Operative versus Non-operative Treatment for Atraumatic Rotator Cuff Tears (ARC) trial data were used and screening and enrollment trends were analyzed before and after the trial was paused due to COVID-19. Demographic data, clinical characteristics, Mental Health Inventory (MHI), Shoulder Pain and Disability Index (SPADI), and the American Shoulder and Elbow Surgeons (ASES) questionnaire scores were evaluated for all individuals who were screened and randomized into the study.

**Results:** Among screened individuals, the proportion identifying as non-Hispanic or non-Latino was higher before the COVID-19-related trial pause (86.68%) than after the pause (75.01%). A lower percentage of individuals with an unknown or not reported ethnicity was observed before the trial was paused (9.56%) than after the trial resumed (21.9%). Notable recruitment findings included a higher proportion of individuals who declined to receive further information about the trial after the COVID-19-related pause (35.08%) than before the pause (6.81%). Additionally, patient-, provider-, and healthcare system-specific barriers to recruitment were identified based on screening and enrollment data.

**Conclusion:** The 20-month pause in this trial due to the COVID-19 pandemic introduced several patient-, provider-, and healthcare system-specific recruitment barriers that may have prolonged the study timeline.

***Keywords:*** COVID-19, musculoskeletal, physical therapy, randomized clinical trial, rotator cuff tears, surgery.

On March 11th, 2020, the World Health Organization (WHO) officially declared novel coronavirus disease 2019 (COVID-19) as a global pandemic.[1] Worldwide, there have been over 770 million cases[2] and over seven million deaths[3] have been attributed to this highly contagious respiratory illness. Also, COVID-19 has caused disruptions to nearly every aspect of our daily lives due to shelter in place restrictions and social distancing requirements. The field of clinical research has been greatly impacted as many clinical trials were paused indefinitely with their research staff being assigned to other duties within their healthcare systems.[4-6] Continuous and robust

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recruitment has always been paramount in clinical trials, particularly those with a surgical arm.

Before the pandemic, Jacques et al.[7] reported that only 63% of randomized-controlled trials met their original recruitment goal. Furthermore, Lim et al.[8] examined enrollment rates of orthopedic randomized clinical trials over a 12-year period and found trials comparing operative versus non-operative treatments had significantly lower enrollment rates compared to trials examining two opposing operative interventions (80% *vs.* 90%, $p < 0.0001$). A significant effect was also observed by region, with enrollment rates for North American trials at 49% compared to trials conducted at other locations (86%, $p < 0.0001$).[8]

Considering the significant recruitment challenges already faced for operative trials, the introduction of a global pandemic produced new circumstances that further complicated how clinical research was conducted. Currently, there is a dearth of literature on how the COVID-19 pandemic has impacted clinical trials examining treatments for rotator cuff tears. In the present study, we, therefore, aimed to examine screening and accrual data from a unique multi-center clinical trial for rotator cuff tears before and after the trial was paused due to the COVID-19 pandemic.

## PATIENTS AND METHODS

The Operative versus Non-operative Treatment for Atraumatic Rotator Cuff Tears (ARC) trial is a pragmatic multi-center randomized clinical trial which began recruitment in 2018.[9] The trial protocol can be accessed elsewhere,[9] but in brief, the trial objectives were to recruit individuals 40 to 84 years of age with atraumatic rotator cuff tears and randomize them to receive either non-operative treatment (physical therapy) or operative treatment (surgery). Additional inclusion criteria included shoulder pain with loss of active motion, strength, or function, magnetic resonance imaging (MRI) confirmed partial or full thickness supraspinatus and/or infraspinatus tear of 4cm or less, medically fit for surgery, and ability to give informed consent. Exclusion criteria consisted of a primary diagnosis other than a rotator cuff tear, history (in the past two years) of shoulder fracture involving the humeral head on affected side, previous rotator cuff surgery on affected side, isolated subscapularis and/or teres minor tear on affected side, acute rotator cuff tear caused by a severe trauma, shoulder used as a weight-bearing joint, contraindication to MRI, glenohumeral osteoarthritis on X-rays/MRI, as determined by recruiting MD, Grade 4 fatty infiltration of rotator cuff (any tendons), candidate for reverse shoulder arthroplasty or total shoulder arthroplasty at baseline, non-English speaking (questionnaires only validated in English), and severe problems with maintaining follow-up expected (including, but not limited to, a history of substance abuse, homelessness/incarceration, dementia, brain injury, and psychotic disorders).

The primary objective of the trial was to assess pain and functional outcome by treatment group and the secondary objective was to assess heterogeneity of treatment effect by age and tear size. Study physicians at each site recruited potential participants from their sports medicine and shoulder clinics. An MRI-confirmed rotator cuff tear was required for study participation. In total, 19 different centers randomized at least one participant into the trial. Recruitment began in March 2018 and continued until March 2020 when it was paused due to the COVID-19 pandemic. During the pause, study operations ceased at all recruitment sites. Recruitment resumed in December 2021 and continued until December 2023. Prior to study, a written informed consent was obtained from each participant. The study protocol was approved by the Vanderbilt University Medical Center, Institutional Review Board (IRB) (Date: November 17, 2017, No: 171863). The study was conducted in accordance with the principles of the Declaration of Helsinki. The study is registered at ClinicalTrials.gov under the registration number of NCT03295994.

Demographic data were collected for all individuals screened for study participation. The reasons why potential participants were deemed ineligible or were not assessed for eligibility by the research staff were also documented. Similarly, demographic data were collected for all participants randomized to the study. The reasons why eligible individuals declined participation or

were not approached by the research staff were also recorded.

This study strictly adheres to the widely accepted Good Trial Practices, as described by Piantadosi[10] and Meinert[11] which encompass data collection and quality assurance, trial conduct and implementation, statistical analysis, and reporting. Research Electronic Data Capture (REDCap) is used for the data collection and management.[12,13]

### Statistical analysis

Statistical analysis was performed using the SAS version 9.4 (SAS Institute Inc., Cary, NC, USA) and RStudio version 2024.12 software (Posit Software, PBC, Boston, MA, USA). Continuous data were presented in mean ± standard deviation (SD) or median and interquartile range (IQR), while categorical data were presented in number and frequency. When expected cell counts were small, the Fisher exact test was used instead of the Pearson chi-square test. Between-group comparisons of continuous variables were performed using the two-sample t-test when the distribution was approximately normal and the Wilcoxon rank-sum test when the normality assumption was not met. Missing observations were not imputed for the descriptive and between-group comparisons. Percentages for categorical variables were calculated using the available observations within each group, and the number of missing observations was reported where applicable. For continuous variables, analyses were based on available observations for each variable. Thus, the number of observations may vary across variables due to the missing data. The extent of missing data was assessed, and missing observations were considered when interpreting the results. A two-sided $p$ value of $< 0.05$ was considered statistically significant.

## RESULTS

Enrollment trends during the pre- and post-COVID-19 periods were summarized in Figure 1. A Consolidated Standards of Reporting Trials (CONSORT) flow diagram illustrating the numbers of patients screened, found eligible, consented, and randomized is presented in Figure 2. For the screened population, reasons for ineligibility or not being assessed were summarized and compared between the pre- and post-COVID-19 periods (Table 1). Variables from the imaging and screening databases were combined to create a common classification of reasons for ineligibility or non-assessment. Among eligible patients, reasons for not being approached or not consenting were also compared between the pre- and post-COVID-19 periods (Table 2).

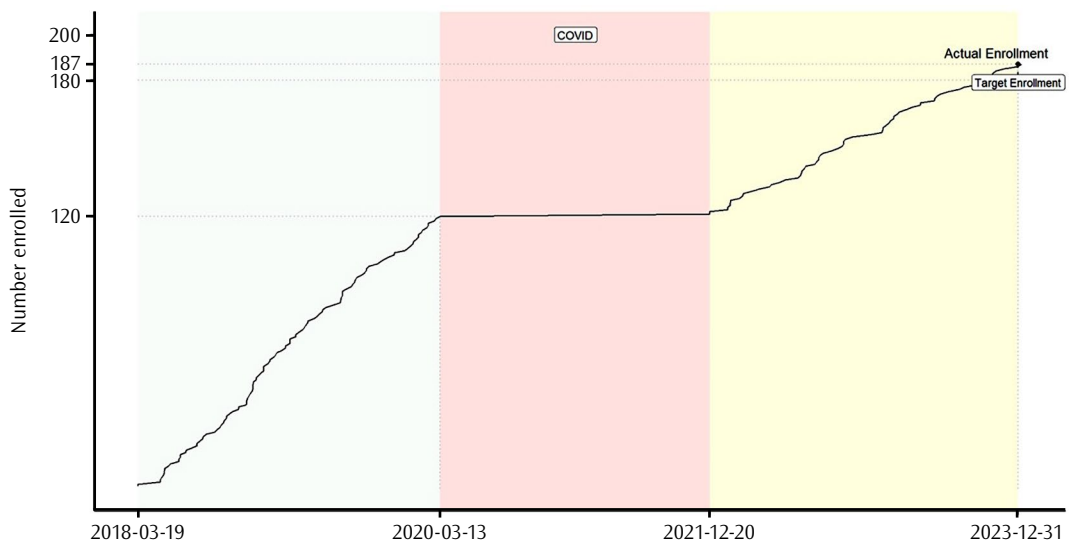



**Figure 1.** Enrollment trend pre- and post-COVID-19.
COVID-19, coronavirus disease 2019.

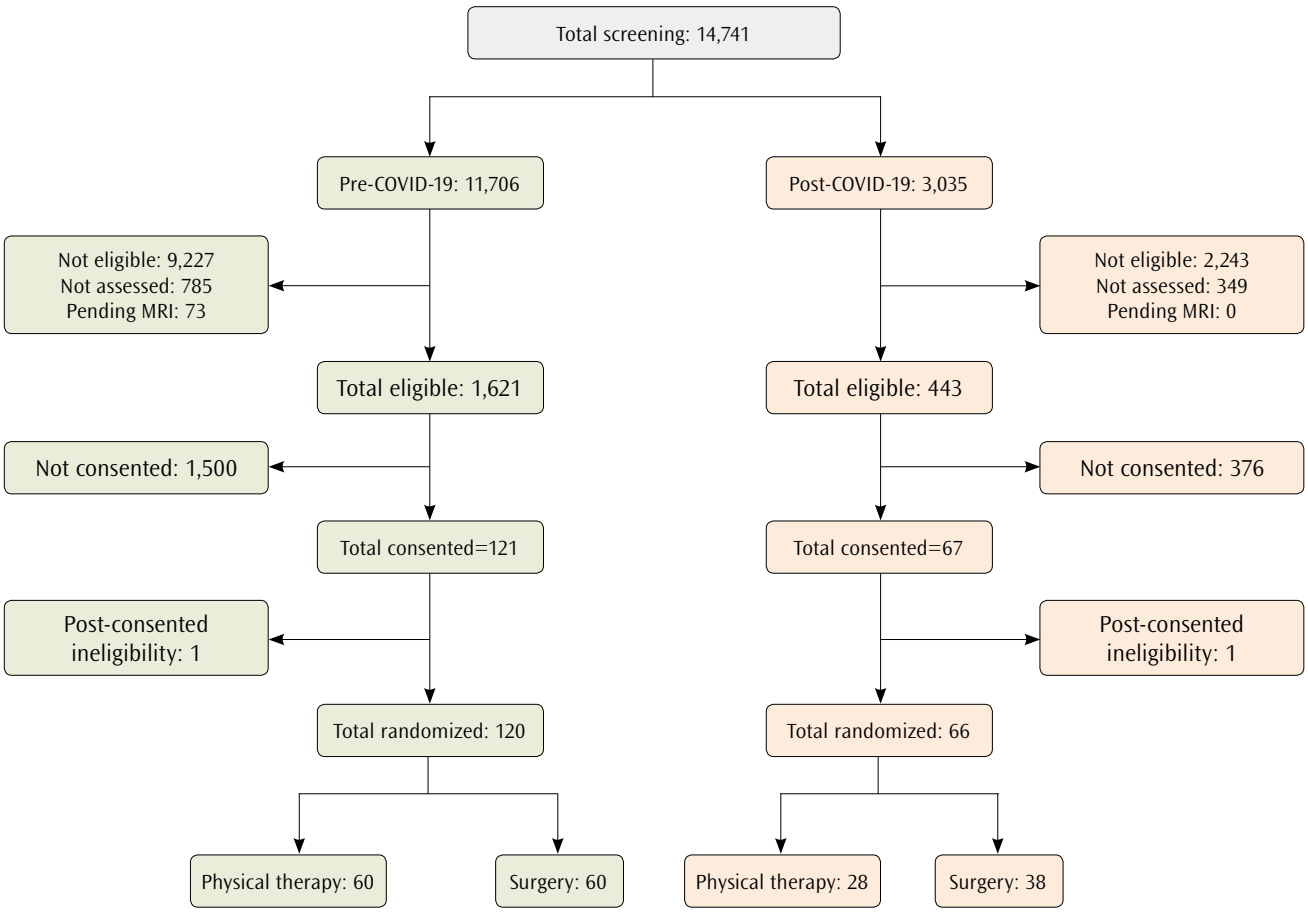



**Figure 2.** CONSORT diagram.
COVID-19, coronavirus disease 2019; MRI, magnetic resonance imaging.

**Table 1. Reasons for patient ineligibility and non-assessment for eligibility among the total screened population**

| | Pre-COVID-19 | | Post-COVID-19 | | Total | |
|---|---|---|---|---|---|---|
| | n | % | n | % | n | *p* |
| **Reason** | | | | | | **< 0.0001** |
| Cuff tear caused by traumatic event | 578 | 6.48 | 213 | 9.31 | 791 | |
| Previous rotator cuff surgery on affected side | 737 | 8.26 | 171 | 7.47 | 908 | |
| Primary diagnosis other than rotator cuff tear | 6493 | 72.79 | 1386 | 60.58 | 7879 | |
| Candidate for reverse or total shoulder arthroplasty | 131 | 1.47 | 11 | 0.48 | 142 | |
| Glenohumeral OA on X-ray or MRI | 58 | 0.65 | 24 | 1.05 | 82 | |
| Grade 4 fatty infiltration | 22 | 0.25 | 12 | 0.52 | 34 | |
| Isolated subscapularis or teres minor tear | 53 | 0.59 | 12 | 0.52 | 65 | |
| Patient cancelled or missed appointment | 350 | 3.92 | 105 | 4.59 | 455 | |
| MD did not complete clinic screening form or form not available | 62 | 0.7 | 14 | 0.61 | 76 | |
| Other reasons | 436 | 4.89 | 340 | 14.86 | 776 | |

COVID-19, coronavirus disease 2019; OA, osteoarthritis; MRI, magnetic resonance imaging; MD, medical doctor; *P* value represents the overall Chi-squared test comparing the distribution of reasons between the Pre-COVID-19 and Post-COVID-19 groups.

Patient demographic characteristics, including age, sex, ethnicity, race, and education, as well as clinical characteristics, including randomization group, treatment pursuit (timeline to receive treatment), Mental Health Inventory (MHI), Shoulder Pain and Disability Index (SPADI), and American Shoulder and Elbow Surgeons (ASES) questionnaire scores, were summarized for the pre- and post-COVID-19 groups (Tables 3 and 4).

Figure 1 shows the enrollment trend pre and post COVID-19 pause. From March of 2018 to March of 2020, a total of 120 participants were randomized into the trial. The trial was paused for approximately 20 months due to COVID-19. An additional 66 participants were randomized into the trial from December of 2021 through the end of study enrollment in December of 2023 for a total of 186 participants. As shown in Figure 2, a total of 14,741 individuals were screened for this study; 11,706 before the COVID-19 pause and 3,035 after the COVID-19 pause. In Table 1, reasons why individuals who were screened for the trial were not eligible or assessed are presented. Of note, a lower percentage of individuals who presented with a rotator cuff tear that was caused by a traumatic event were observed before the COVID-19 pause (6.48%) than after the pause (9.31%). A higher percentage of screened individuals were deemed ineligible due to previous rotator cuff surgery on the affected side before the COVID-19 pause (8.26%) as opposed to after (7.47%). Additionally, a greater percentage of

**Table 2. Reasons for non-approach or non-consent among eligible patients**

| | Pre-COVID-19 | | Post-COVID-19 | | |
|---|---|---|---|---|---|
| | n | % | n | % | *p* |
| **Reason** | | | | | **< 0.0001** |
| Patient is not interested in hearing more about the study | 115 | 6.81 | 201 | 35.08 | |
| Already had Physical therapy | 184 | 10.9 | 13 | 2.27 | |
| Not willing to be randomized/wants to decide own treatment | 1012 | 59.98 | 218 | 38.05 | |
| Other* | 376 | 22.31 | 141 | 24.6 | |

COVID-19, coronavirus disease 2019. * Other contains category such as patients is busy, as per MD patient needs surgery, as per MD tear not appropriate for surgery, prefers not to/reason not specified, not able to pursue treatment, insurance issues, missed/skipped appointment, will not follow treatment protocol, wants physician to decide, unable to determine outcome of patient.

**Table 3. Demographic characteristics of total screened population**

| | Pre-COVID-19 | | Post-COVID-19 | | |
|---|---|---|---|---|---|
| | n | % | n | % | *p* |
| Sex | | | | | 0.2681 |
| Female | 5,970 | 50.9 | 1,603 | 49.58 | |
| Male | 5,731 | 48.86 | 1,619 | 50.08 | |
| Unknown/not reported | 28 | 0.24 | 11 | 0.34 | |
| Ethnicity | | | | | < 0.0001 |
| Non-Hispanic or non-Latino | 10167 | 86.68 | 2425 | 75.01 | |
| Hispanic or Latino | 441 | 3.76 | 100 | 3.09 | |
| Unknown/not reported | 1121 | 9.56 | 708 | 21.9 | |
| Race | | | | | < 0.0001 |
| White | 9,211 | 78.53 | 2327 | 71.98 | |
| African American | 820 | 6.99 | 337 | 10.42 | |
| Other | 1,360 | 11.6 | 462 | 14.29 | |
| Unknown/not reported | 338 | 2.88 | 107 | 3.31 | |

COVID-19, coronavirus disease 2019.

individuals with a diagnosis other than rotator cuff tear were observed before the trial was paused (72.79%) than after (60.58%).

Table 2 depicts the demographic characteristics of the total screened population. The sex of screened individuals was not significantly different before or after the COVID-19 pause. However significant differences were noted for ethnicity and race. The proportion of individuals identifying as non-Hispanic or non-Latino was higher before the COVID-19-related trial pause (86.68%) than after the pause (75.01%). A lower percentage of individuals with an unknown or not reported ethnicity were observed before the trial was paused (9.56%) than after the trial resumed (21.9%). The race variable revealed a higher percentage of Whites (78.53%) were screened before the trial was paused as opposed to after (71.98%). For African Americans, a lower percentage (6.99%) were screened before the COVID-19 pause than after (10.42%).

In Table 3, the reasons why a potential participant was not approached by research staff or consented into the trial are shown. A higher percentage of individuals stated that they were not interested in hearing more about the trial after the COVID-19 pause (35.08%) than before (6.81%). A greater percentage of individuals already received physical therapy before the trial pause (10.9%) as opposed to after (2.27%). Further, individuals who were not willing to be randomized or declared to choose their own

**Table 4. Demographic characteristics of total randomized population**

| | Pre COVID-19 | | | | Post COVID-19 | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | n | % | Mean ± SD | Min-Max | n | % | Mean ± SD | Min-Max | *p* |
| Age (year) | | | 63.75 ± 7.42 | 50-84 | | | 60.79 ± 8.43 | 40-77 | 0.0558 |
| Sex | | | | | | | | | 0.1054 |
| Female | 67 | 55.83 | | | 45 | 61.16 | | | |
| Male | 53 | 44.17 | | | 21 | 31.34 | | | |
| Missing | 0 | 0 | | | 1 | 1.49 | | | |
| Ethnicity | | | | | | | | | 0.6096 |
| Hispanic/latino | 6 | 5 | | | 5 | 7.46 | | | |
| Missing | 4 | 3.33 | | | 1 | 1.49 | | | |
| Non-Hispanic/Latino | 110 | 91.67 | | | 61 | 91.04 | | | |
| Race | | | | | | | | | 0.0494 |
| White | 96 | 80 | | | 43 | 64.18 | | | |
| African American | 15 | 12.5 | | | 18 | 26.87 | | | |
| Others | 5 | 4.17 | | | 4 | 5.96 | | | |
| Unknown/not reported | 4 | 3.33 | | | 2 | 2.99 | | | |
| Education | | | | | | | | | 0.3462 |
| College | 35 | 29.17 | | | 23 | 34.33 | | | |
| Community college | 37 | 30.83 | | | 14 | 20.9 | | | |
| Graduate degree | 22 | 18.33 | | | 15 | 22.39 | | | |
| High school | 21 | 17.5 | | | 15 | 22.39 | | | |
| Less than high school | 4 | 3.33 | | | 0 | 0 | | | |
| Missing | 1 | 0.83 | | | 0 | 0 | | | |
| Randomization group | | | | | | | | | 0.2809 |
| Physical therapy | 60 | 50 | | | 28 | 41.79 | | | |
| Surgery | 60 | 50 | | | 39 | 58.21 | | | |
| Treatment pursuit | | | | | | | | | 0.0005 |
| Assigned treatment pursued within 2 months | 86 | 71.67 | | | 33 | 49.25 | | | |
| Assigned treatment pursued within 2-12 months | 11 | 9.17 | | | 11 | 16.42 | | | |
| Crossover | 10 | 8.33 | | | 7 | 10.45 | | | |
| No treatment in 12 months | 13 | 10.83 | | | 8 | 11.94 | | | |
| Pending assigned treatment < 12 months | 0 | 0 | | | 8 | 11.94 | | | |
| MHI-5 score[1] | | | 77.56 ± 16.32 | 0-100 | | | 75.97 ± 21.71 | 15-100 | 0.6807 |
| SPADI score[2] | | | 50.81 ± 20.84 | 11-98.75 | | | 54.54 ± 24.91 | 5.25-97.5 | 0.3742 |
| ASES score[3] | | | 49 ± 18.06 | 6.66, 90 | | | 46.41 ± 23.56 | 5-96.66 | 0.4203 |

COVID-19, coronavirus disease 2019; SD, standard deviation; MHI, Mental Health Inventory; SPADI, Shoulder Pain and Disability Index; ASES, American Shoulder and Elbow Surgeons; [1] Mental Health Inventory; [2] Shoulder Pain and Disability Index; [3] American Shoulder and Elbow Surgeons.

treatment was higher before the COVID-19 pause (59.98%) than post-COVID-19 pause (38.05%). There were also statistically significant differences for both race and treatment pursuit. For race, a greater percentage of individuals identifying as White were randomized before the COVID-19 pause (80%) as opposed to after (64.18%). On the other hand, fewer study participants identifying as African American were randomized before the COVID-19 pause (12.5%) than after the trial pause (26.87%). The treatment pursuit variable revealed a higher percentage of participants pursued their assigned treatment intervention within two months before the trail was paused (71.67%) than after the trial resumed (49.25%). The remaining demographic variables showed no significant differences (Table 4).

Some of our findings represent barriers to recruitment or study conduct that could be attributed to decisions made by the patient, the provider, or the healthcare system. Among patient-specific barriers, the proportion of individuals who declined to receive further information about the trial was higher after the COVID-19-related trial pause (35.08%) than before the pause (6.81%). However, the proportion of individuals who were unwilling to be randomized or preferred to choose their own treatment was higher before the pause (59.98%) than after it (38.05%). Among provider-specific factors, a higher proportion of individuals already received physical therapy before the trial pause (10.9%) than after the pause (2.27%). Regarding healthcare system-related factors, 71.67% of participants were able to initiate their assigned treatment within the first two months after randomization before the pause. This proportion decreased to 49.25% after the pause.

## DISCUSSION

In the present study, we assessed the impact of the pause due to the COVID-19 pandemic on a large multi-center clinical trial on rotator cuff tears. The main finding of this study was that patients were less agreeable to learn more about participating in the trial after the COVID-19 pause than they were before the pause. The pause that this clinical trial experienced due to the COVID-19 pandemic resulted in many challenges that adversely affected staffing, recruitment, and the scheduling of study procedures. These findings suggest that the trial pause added additional logistical and operational challenges to the investigation.

Barriers to study participation that are specific to the patient include not meeting the inclusion/exclusion criteria during the screening process, choosing not to learn more about the study after it was introduced to them by their physician, and choosing not to participate after they learned about the specifics of the study and were deemed eligible by research staff. With the exception of *"Patient cancelled or missed their appointment"* and *"Physician did not complete clinic screening form"*, Table 1 summarizes reasons why a patient who presented to the clinic was not eligible due to not meeting the inclusion/exclusion criteria. Although these barriers were patient-specific, they could not be controlled, as they reflected the nature and severity of the patients' injuries. There were no significant differences in the screening data presented in Table 1 other than a 12% drop in patients presenting with a primary diagnosis other than rotator cuff tear after the COVID-19 pause. The reason for this discrepancy is unknown, but could be due to the usual clinic flow, patient reluctance to access healthcare facilities, or longer than normal wait times at imaging centers due to scheduling back-up due to the pandemic.

The barriers to study participation presented in Table 2 represent reasons why patients who met eligibility criteria after the screening process chose not to participate. Before the COVID-19 pause, only 6.81% of patients were unwilling to learn more about the study after it was introduced to them by their physician, this number jumped to 35.08% after the COVID-19 pause. This number is alarming, as it could represent a potential shift in patients' attitudes toward study participation after the COVID-19 pause. When a patient agreed to learn more about the study after it was introduced to them by their physician, a member of the research staff approached the patient and the recruitment process moved forward, if they did not agree, the recruitment process stopped. As previously mentioned, operative clinical trials already face increased recruitment barriers, an

increase in the number of patients who are not agreeable to clinical trial participation has the potential to negatively impact recruitment goals and extend study timelines. A systematic review by Lin et al.[14] examined refusal rates for pragmatic and comparative effectiveness studies and found 32% of individuals refused trial participation, which is on par with our rate after the COVID-19 pause. In this study, the investigator discussed the trial with potential participants and answered any questions regarding the evidence supporting operative and non-operative treatments for rotator cuff tears. It is unclear why a higher percentage of individuals were unwilling to be presented with additional information about the study from the research assistant after the COVID-19 pause.

Furthermore, in Table 2, 59.98% of individuals who were not willing to be randomized to the study reported that they demanded to choose their own treatment as their main reason for declining participation, as opposed to 38.05% after the COVID-19 pause was lifted. At the height of the pandemic, many elective orthopedic surgeries were cancelled by hospital systems.[15] A nested cross-sectional study by Mittal et al.[16] examined the willingness of individuals to be randomized into the Combined Randomized and Observational Study of Surgery for Type B Ankle Fracture Treatment (CROSSBAT) trial. In this study, 113 individuals agreed to be randomized and those unwilling to be randomized (n = 199) were offered participation in an observational cohort. Of the 199 who declined randomization, the main reasons cited were being worried of receiving a treatment by chance and a higher preference of receiving one treatment over the other. In addition, Spierenburg et al.[17] surveyed 100 patients visiting an orthopedic clinic and asked them if they were willing to participate in a hypothetical clinical trial, either invasive or diagnostic, for individuals with a distal radius fracture. The authors found no significant difference in participant willingness for either the diagnostic (68/100) or invasive (66/100, $p = 0.76$) clinical trial. Patients who agreed to participate primarily cited their desire to contribute to scientific research as their motivation, whereas those who declined participation did so without consulting a physician for additional information. A study by Creel et al.[18] found a strong association between treatment preference (operative *vs.* non-operative) and willingness to participate in a hypothetical randomized clinical trial, with individuals who had a strong treatment preference being less willing to participate.

Additional patient-specific barriers depicted in Table 2 were grouped under the 'Other' category, as none individually ranked among the top three barriers. These included patients being busy, preferring not to specify or not specifying a reason, missing or skipping appointments, being unable to pursue treatment, experiencing insurance-related issues, being unwilling to follow the treatment protocol, and preferring the physician to make the treatment decision. Although these barriers were noteworthy, their overall prevalence did not differ significantly before (22.31%) and after (24.6%) the trial pause.

In Table 1, a barrier to study participation which could be attributed to the provider during the screening process was *"Physician did not complete clinic screening form"*. The study physician was responsible for completing a screening form to assess the potential participant's medical eligibility for the trial following the clinical examination and submitting the form to the research assistant. On occasion, the study physician neglected to complete this task; however, it was relatively rare and did not appreciably differ from before the trial was paused (0.7%) to after (0.61%).

In Table 2, a barrier that could, at least partially, be attributed to the provider is *"Already had physical therapy"*. Patients who participated in physical therapy for their rotator cuff tear were ineligible for this trial. Prior to the study pause, 10.9% of patients were ineligible for the trial, as opposed to 2.27% after the re-start of the trial. Providers were more likely to prescribe physical therapy to their patients, and the patients were more likely to attend physical therapy before the pandemic. This finding is reasonable, as many patients may not have felt comfortable going to physical therapy clinics during the COVID-19 pandemic due to contact precautions, even if prescribed by their provider. Physicians may have discussed with their patients their willingness to

attend physical therapy, if prescribed, during the COVID-19 period; however, this aspect was not explored in depth in the present investigation.

Additional barriers that could be attributed to the provider in the 'Other' category of Table 2 are *"As deemed necessary by the physician, the patient required surgery"* and *"The patient was deemed unsuitable for surgery by the physician"*. These barriers, which did not differ significantly before or after the trial pause, represent the professional opinion of the study physician based on their clinical examination of the patient.

Barriers to patient recruitment tied to decisions made by hospitals during the pandemic are grouped as system specific barriers. As mentioned above, many hospitals made the decision to temporarily suspend elective orthopedic surgeries during the COVID-19 pandemic.[15] As a result, many of our sites experienced a loss of research staff during COVID-19 and they had difficulty in hiring new research staff after the trial restarted. Some sites did not resume recruitment after the pause and new sites were eventually added to bolster recruitment. However, site initiation and onboarding required time, and proficiency in study procedures was not always achieved quickly. The overall impact that COVID-19 had on screening and recruitment for this trial can clearly be seen in Figure 2. Despite similar time frames, 79% of the total number of individuals screened for this study were evaluated before the trial was paused. Similarly, 64% of participants were randomized before the COVID-19 pause.

The most significant challenge following the resumption of recruitment after the COVID-19-related delay was achieving the pre-delay recruitment volume. Taken together, the suspension of elective orthopedic surgeries at some hospitals and the reassignment of research personnel to non-research duties may have contributed to the participant recruitment challenges observed in this study.

In Table 4, 71.67% of participants were able to pursue their assigned treatment within the first two months of being randomized. After the break, this number dropped to 49.25%. An operational objective of this study was to ensure that patients received their assigned treatment (surgery or physical therapy) within two months of randomization. Although the backlog resulting from the suspension of elective orthopedic surgeries did not constitute a barrier to study participation, it delayed the timely implementation of study procedures. Given the unprecedented and challenging circumstances faced by hospitals, these decisions were entirely understandable, and the investigators had limited opportunities to mitigate their impact.

Recruiting a diverse participant population is essential to ensure the generalizability of study findings. As aforementioned, this study experienced some variability in the race and ethnicity of individuals screened and randomized before and after the re-start of the trial.

Overall, the racial composition of the randomized study population was consistent with current United States (US) Census data, with White and African American individuals accounting for 74% and 17% of the population, respectively.[19] Among screened participants, the percentage of patients whose ethnicity was reported as 'Unknown' or 'Not Reported' jumped from 9.56% before the COVID-19 pause to 21.9% after the pause. It is unclear why this discrepancy occurred, but could be attributed to patient comfort in reporting their ethnic background or possibly missing from the electronic medical record, which was the primary source of screening information. For ethnicity, our randomized study population of those identifying as Hispanic or Latino (5.88%) fell short of the 19.5% currently residing in the US.[20] The proportion of individuals identifying as Hispanic or Latino increased by 23% between the 2010 and 2020 US censuses. Two recruiting sites for this investigation are in large urban areas and are considered safety-net hospitals that serve a racially and ethnically diverse patient population, many of which are under-insured or have no health insurance at all. Despite the inclusion of these centers, recruitment of Hispanic and Latino participants fell short of expectations.

In an attempt to bolster recruitment after the COVID-19 pause, the study partnered with an external organization to launch a nationwide social media campaign. Study advertisements were posted on social media platforms, and

interested individuals were referred to the nearest participating clinical site. The coordinating center and the external marketing organization collaborated with the study's Stakeholder Advisory Board to develop messaging tailored to the target population. Several referrals were obtained from the campaign, but they did not result in any patients being randomized into the trial. The limited success of the recruitment campaign may have been attributable to the logistical challenges associated with participation. Patients were required to travel to a clinical site for an evaluation appointment and, if randomized to the surgical arm, return for surgery and postoperative care. In contrast, physical therapy could be performed at a location convenient for the patient.

The preferred recruitment strategy for the study was to recruit patients in clinic after they were seen and deemed eligible by the study physician. However, some patients were unwilling or did not have time to discuss the study with the research assistant after their appointment; therefore, remote recruitment was employed. Electronic consent was approved by the IRB for this study, moderate recruitment increases were observed, particularly for clinical sites who did not have the opportunity of having recruiters in clinic on a consistent basis.

The use of social media and online recruitment methods have been shown in the literature to be effective methods for patient accrual.[21,22] However, despite the use of these alternative strategies, face-to-face recruitment in clinic was the most fruitful approach. Agreeing to participate in a clinical trial that included a surgical arm represented a significant decision for potential participants. The opportunity to discuss the trial with study staff and ask questions in person may have contributed to the greater success of this recruitment method.

Several lessons were learned from this experience. In retrospect, several strategies could have been implemented from the outset of the trial to maximize recruitment, irrespective of the pandemic. As operative trials are difficult to recruit for, investigators should employ comprehensive recruitment methods from the start. The ability to recruit both in-person and remotely is vital. Study consent forms should have been available for both electronic and paper-based signatures to accommodate potential participants' preferences. This trial screened more than 14,000 individuals but randomized fewer than 200. These findings highlighted the need for investigators to adopt a broad recruitment strategy to enroll the required number of participants while maintaining opportunities for personalized consultation with individuals considering participation in a trial involving a surgical intervention.

Furthermore, this trial included two safety-net hospitals in large urban centers, but still fell short of including enough Hispanic and Latino participants to match the demographic make-up of the US. Employing bilingual research staff and having study forms available in Spanish at clinical sites could have helped study recruitment in this area. The inclusion of additional safety-net hospitals could also have increased the diversity of our randomized study population. Investigators should work to develop comprehensive and diverse recruitment plans to reach a study population that is generalizable to the US population.

The main limitation to this study is that it is descriptive in nature; therefore, causality cannot be established for any of the variables examined in this study, and no hypothesis was tested. While this is a multi-center study, generalizability is limited for patient populations outside of the inclusion/exclusion criteria of this study. Our findings were intended to describe the challenges encountered by our team in conducting a clinical trial during the COVID-19 pandemic and may not be generalizable to clinical trial conduct in the post-pandemic setting.

In conclusion, the pause our clinical trial experienced due to the COVID-19 pandemic resulted in many challenges which adversely affected staffing, recruitment, and the scheduling of study procedures. Re-starting a large-scale, multi-center clinical trial after halting it for 20 months was an arduous and complex task that took several months before recruitment could be resumed. These results suggest that individual's willingness to participate in clinical research may have been affected by the pandemic, as participant recruitment did not return to pre-pause levels following the resumption of recruitment.

The underlying reasons are complex and may have included disruptions to therapy services and the cancellation of elective procedures at many participating sites during the pandemic. These challenges are not unique to this study, and the disruptions were likely felt by clinical researchers around the world. Musculoskeletal clinical trials are complex, and recruitment is challenging. The prolonged pause in this trial due to the COVID-19 pandemic substantially affected patient screening and recruitment and extended the overall study timeline.

**Declaration of Conflicting Interests**

The authors declare that there are no conflicts of interest with respect to the research, authorship, and/or publication of this article.

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**Author Contributions**

M.A.N.: Manuscript drafting, data collection, data analysis; R.P., F.D.A.: Manuscript drafting, statistical and data analysis; N.B.J.: Study conception and design, manuscript drafting, data collection, data analysis.

**Data Availability**

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

**AI Disclosure**

The authors declare that artificial intelligence (AI) tools were not used, or were used solely for language editing, and had no role in data analysis, interpretation, or the formulation of conclusions. All scientific content, data interpretation, and conclusions are the sole responsibility of the authors. The authors further confirm that AI tools were not used to generate, fabricate, or 'hallucinate' references, and that all references have been carefully verified for accuracy.

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