

COVID 19 and its Effects on Pediatric Orthopaedic Clinical Trials

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INTRODUCTION

- The number of pediatric orthopaedic cases continues to rise.
- Clinical trials for the treatment of these cases are critical to enhance the quality of life of these children.
- In response to the COVID-19 pandemic, the FDA updated guidance on conducting clinical trials to prioritize patient safety.
- The disruption of pediatric orthopaedic-related clinical trials due to the COVID-19 pandemic has not previously been evaluated.

OBJECTIVE

- Our objective is to quantify the amount of pediatric orthopaedic-related clinical trials disrupted due to the COVID-19 pandemic.

METHODS

- ClinicalTrials.gov was searched for ongoing and discontinued trials between 01/01/2020 - 10/31/2021.
- Trials were screened for relevance to the study and the number of participants, trial location, funding source, and reason for discontinuation.
- Inclusion criteria: Clinical trials that involved Orthopaedic related disorders with pediatric patients
- Associations were evaluated using Mann-Whitney U tests or ANOVA, where appropriate.

RESULTS

- Our search returned 544 trials, of which 128 were included with a total of 15,194 participants. Of the included trials, 9 were discontinued (7%) with a total of 497 participants. Of the 9 discontinued trials, 3 (33.3%) stated COVID-19 as a reason and these trials accounted for 64 participants (12.9% of participants). (Figure 1)
- The Mann-Whitney U test and ANOVA showed no statistically significant difference in enrollment between trials discontinued due to COVID-19 compared to other discontinued trials, nor among funding, or location (Table 1).

FIGURES/TABLES

Pediatric Orthopaedic Trial discontinuation amidst the COVID-19 Pandemic

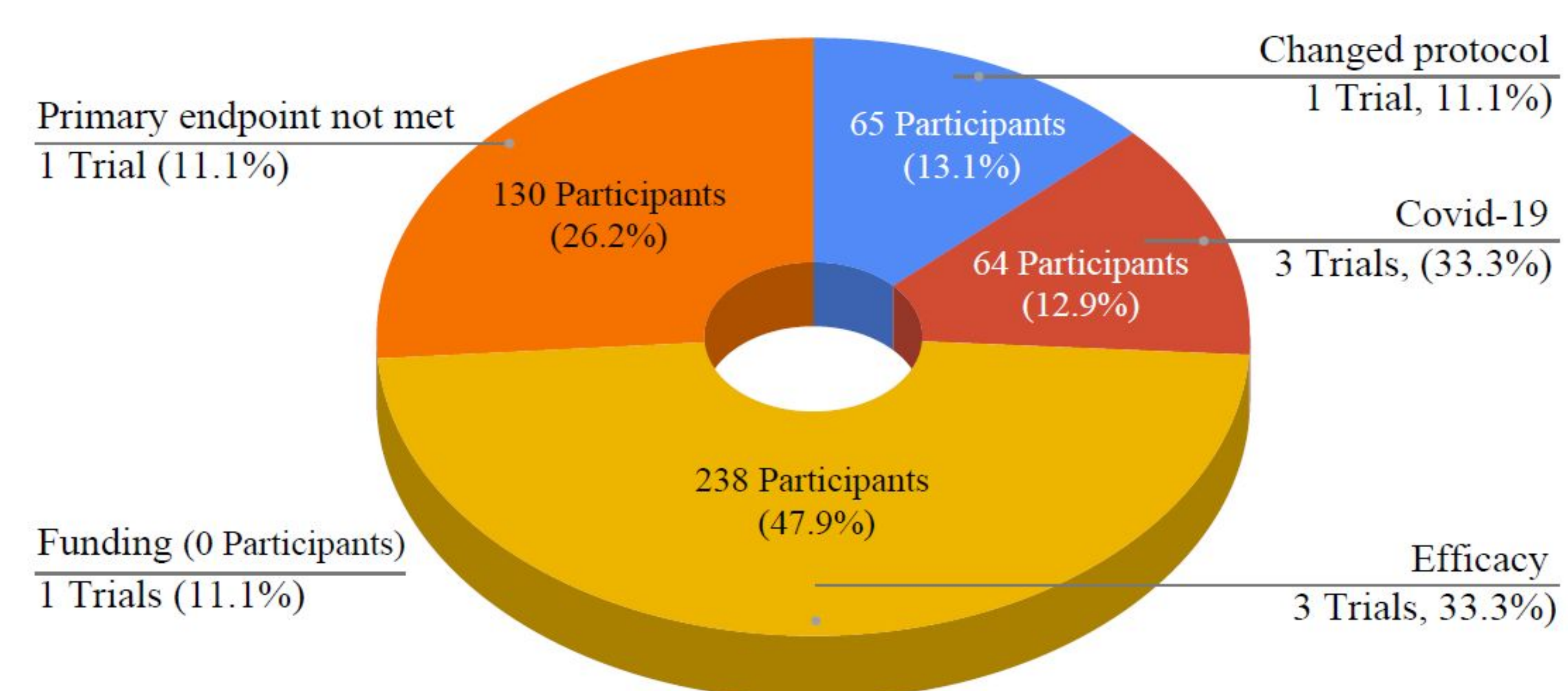


Figure 1

Table 1. Characteristics of discontinued Pediatric Orthopedic trials during the Pandemic

	No. of Trials	Percent	Enrollment	Percent
Location:				
US	6	66.7%	476	95.8%
Non-US	3	33.3%	21	4.2%
Funding source:				
Industry	6	66.7%	412	82.9%
Government	0	0.0%	0	0.0%
Other	3	33.3%	85	17.1%

DISCUSSION & RECOMMENDATIONS

- The overall rate of discontinuation for trials in our sample was relatively low compared to expected rates (~25%), suggesting that pediatric orthopaedic clinical trials were resistant to discontinuation
- The low rate of discontinuation may be a result of the relatively low numbers of pediatric clinical trials at baseline.
- Pediatric trials may have more been more likely to be considered emergent or necessary, possibly protecting trials from discontinuation.
- Discontinued trials affected approximately 12% of all children who were enrolled in a clinical trial during this time, possibly leaving trial participants without treatment.
- A limitation of our study is that trialists self-reported reasoning for discontinuation. Many were brief and lacked adequate detail to attribute failure of the trial's completion to a single source.
- We recommend future clinical researchers to provide an adequate amount of detail, thus allowing a proper assessment of trial discontinuation to prevent research redundancy.
- We recommend that future works investigate the factors that made pediatric orthopedic clinical trials resistant to discontinuation during the pandemic.
- Future studies are also needed to assess the long term impact of trial discontinuation on the participants of trials discontinued due to the pandemic.
- These findings highlight the importance of developing safety strategies to continue research during global emergencies.

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