

Effect of COVID restrictions on non-COVID-19 related clinical research



Background



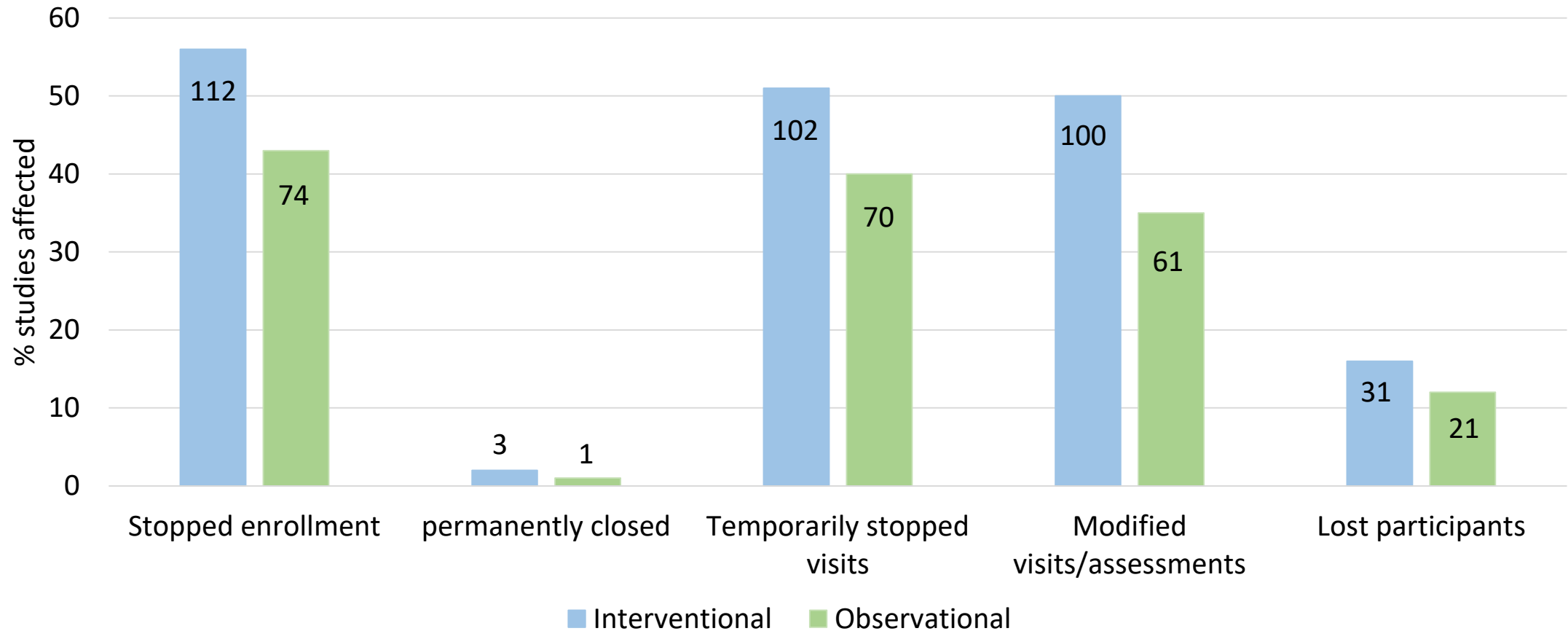
- In Washington, cases of SARS-CoV-2 started appearing the end of February 2020 and increased rapidly the first weeks of March to around 350 cases/day
- March 16 - Guidance for NIH-funded Clinical Trials and Human Subjects Studies Affected by COVID-19 was issued by the NIH
- March 19 – University of Washington and Seattle Children’s Hospital issue work-restrictions related to risk-reduction for COVID-19

Survey



- Multiple choice and open-ended REDCap survey emailed
 - Seattle Children's Research Institute investigators and research staff on May 12, 2020
 - University of Washington investigators on July 6, 2020
- Surveys were completed by 233 respondents
 - Seattle Children's Research Institute: 182 total responses – 84 faculty
 - University of Washington: 51 total responses – 47 faculty
- Overall response rate: 17%

Studies impacted: interventional n=200 observational n=174



Most common modifications used to continue study activities



	n=105
Conducting virtual visits	53 (50)
Use of remote consenting	43 (41)
Widening study visit intervals	41 (39)
Omitting some study procedures	38 (36)
Modifying study procedures	35 (33)
Switching to online surveys	19 (18)
Introducing or enhancing use of technologies	17 (16)
Changing to office or home-based procedures	16 (15)

Barriers to implementing study changes



- Time it took to make the necessary changes:
- Concerns about privacy from both the participant side
 - e.g. participants not wanting to give out their e-mail addresses
- And from the staff side
 - e.g. staff now working from home and not wanting to use their personal cell phones to contact people

Effect on participant experience



- The effect on participant retention was equally positive and negative:
 - 20% reporting negative changes in participant retention
 - 23% reporting positive changes
- Participants liked the flexibility of virtual visits and lack of need to travel
- Conducting remote study visits facilitated enrollment for participants who lived at a distance
- Participant access to the necessary technology was cited most frequently as an issue by the faculty for which the question was relevant (21/42)

Summary of Qualitative Themes



- Research impact - positive
 - Remote procedures have increased efficiency and ease of data collection, easing participant burden as well
 - Enhanced flexibility has increased family responsiveness to research participation
 - “If supported properly and we can get families equipped with devices, telehealth options and online surveys/e-consenting are potentially more convenient and feasible, especially those who live all over Washington state.
 - New research and grant opportunities related to COVID-19 research