

# Feasibility of virtual intervention trials in children with Down syndrome

Colleen Keohane<sup>1</sup>, Chelsea La Valle<sup>1</sup>, Marie Canty<sup>1</sup>, Carol Wilkinson<sup>1</sup>, Nicole Baumer<sup>2</sup>

<sup>1</sup>Boston Children's Hospital Down Syndrome Program, <sup>2</sup>Sie Center for Down Syndrome, Children's Hospital Colorado, University of Colorado

## BACKGROUND

- Inequities in intervention accessibility and the COVID-19 pandemic expose a need for flexible intervention delivery.
- Virtual intervention has previously been explored in children with autism spectrum disorder (ASD).
- Little is known about the feasibility of virtual behavioral interventions in children with Down syndrome (DS).

## OBJECTIVE

To examine the feasibility of a virtual behavioral intervention format in a fully remote clinical trial for children with Down syndrome.

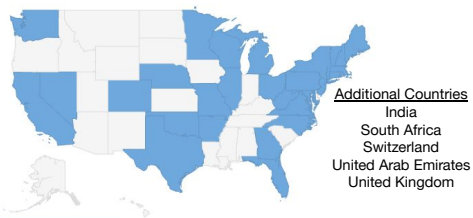
## RECRUITMENT

Table 1. Participant characteristics

	Mean (range) or n(%)
n	103
Age (months)	54.3 (36.2-88.7)
Female	55 (57.9%)
Hispanic or Latino/a	*15 (15.8%)
White	*85 (89.47%)
Asian, Asian Indian	*9 (9.5%)
African American or Black	*7 (7.4%)

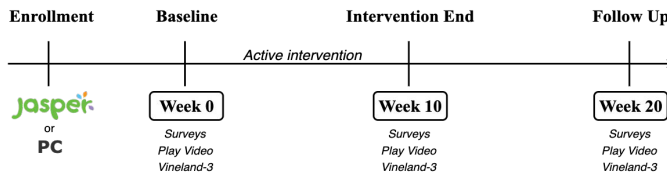
\*missing race/ethnicity information (n = 8)

## RECRUITMENT SCOPE



## METHODS

**Study design:** Participants were randomized into 10 weeks of virtual behavioral intervention (Joint Attention, Symbolic Play, Engagement, and Regulation (JASPER) 1:1 coaching) or a self-lead caregiver psychoeducational curriculum (PC), with follow up at 20 weeks.



**Caregiver Feedback:** The Caregiver Expectancies and Beliefs survey was sent on a weekly/biweekly basis. Q29-32 about benefits and challenges of JASPER strategies were inductively coded for key themes of remote JASPER intervention feasibility (n = 39, 79.6%).

30. What do you think was the most useful aspect of this week's intervention strategies and materials?	
Feedback Example	Code Example
"It was easy to work into our routine"	Benefit: Time
"This week was hard with being sick."	Challenge: Schedule
31. What do you think was the least helpful aspect of this week's intervention strategies and materials?	
Feedback Example	Code Example
"It was all helpful but challenging to figure out how to operationalize in our home as we have 5 children at home"	Challenge: Home Environment
"Video upload hard and takes a lot of time"	Challenge: Recording
"Probably the survey :)"	Challenge: Survey

## RESULTS

Fig.1. Participant Retention

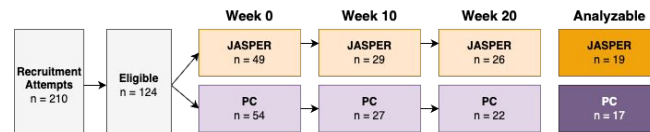


Fig. 2. Assessment Completion Status Over Time by Group

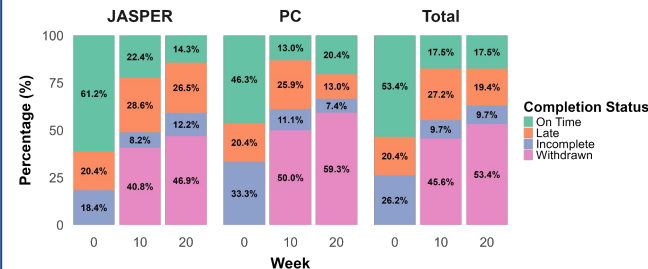
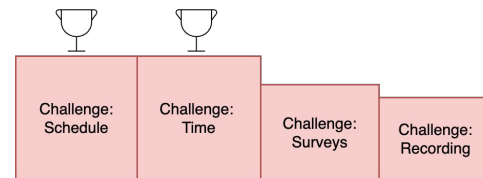


Fig.3 Key Feedback Themes



## CONCLUSIONS

- Despite a wide recruitment effort, logistical challenges of virtual behavioral intervention trials can risk data integrity and increase participant burdens.
- Methodological barriers can lead to **high levels of withdrawal and delayed or incomplete assessment submissions** within a clinical trial of children with DS.
- Main challenges of the remote intervention format were related to **scheduling and time commitment**, as reported by caregivers, and future remote intervention research should consider **flexible scheduling** and a **reduced assessment load** to support children with DS and their families.