



# ECHO

Environmental influences  
on Child Health Outcomes

A program supported by the NIH

**IDeA States  
Pediatric Network**

## **Study Summary**

### **Conducting a Pediatric Randomized Clinical Trial During a Pandemic: A Shift to Virtual Procedures**

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#### **Why was this study conducted?**

In the United States, children living in rural areas have higher rates of being overweight. Unfortunately, children from rural areas seldom participate in clinical research trials. A clinical research trial on changing lifestyle behaviors in rural children who were overweight started in early 2020 but, due to the COVID-19 pandemic, had to switch to virtual procedures instead of in-person visits. Sharing the solutions to problems faced and the lessons learned in completing this trial may help other research teams recruit participants living in rural areas.

#### **What was done?**

The study's goal was to enroll 128 children aged 6 to 12 years old and one parent at four rural clinics over 10 weeks. However, the trial was paused after 6 weeks due to COVID-19. Over the next 12 weeks, the trial resumed using virtual visits where investigators completed enrollment, obtained informed consent, and assessed height and weight of children. Because all study activity was virtual, digital scales and height measurement equipment were shipped to participants' homes, and a second virtual visit was conducted to monitor these measurements. Some participants who did not have internet and needed support for virtual visits received internet-enabled tablets.

#### **What was found?**

When the trial was paused, 42 patients had been enrolled. When the trial resumed virtually, 28 of the 42 continued in the trial, and an additional 89 new participants were enrolled for a total of 117 children. Flexibility was key to solving problems and continuing to enroll and retain participants.

The investigators discovered the challenges and benefits of conducting a virtual trial of this nature. Some challenges to conducting a virtual trial include unreliable equipment delivery, unreturned study equipment, slow Internet speeds and/or poor Internet access in rural areas, and the added costs of buying and shipping equipment and mailing other study materials. However, the benefits of a virtual trial included the ability to conduct study visits at other times of the day, including evenings and weekends. For example, research

staff could conduct study visits at any time of the day, and study-related travel was limited.

### What do the results mean?

The lessons learned from this trial can be applied by any study team recruiting participants from rural areas for a clinical trial. These include:

- Virtual visits and procedures enable successful recruitment and retention of participants from rural areas.
- Research teams must be agile, flexible, and willing to adapt study procedures to meet clinic resources and unanticipated situations.
- While there are considerable additional expenses for buying and shipping study equipment to participants, these costs may be offset by decreased travel to and from rural areas by study staff.

### Who sponsored this study?

This research was supported by the Environmental influences on Child Health Outcomes (ECHO) program, the Office of the Director, National Institutes of Health.

**Appreciation:** The authors appreciate the children, families, and clinics whose participation made the research possible.

You can read the full publication here:

<https://bmcmmedresmethodol.biomedcentral.com/articles/10.1186/s12874-022-01705-7>

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