OPTIMIZING THE **MANAGEMENT OF** PAIN AND **IRRITABILITY IN** CHILDREN WITH **SEVERE** NEUROLOGICAL **IMPAIRMENT: PHASE I**

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INTRODUCTION

The study's purpose is to develop and evaluate a new clinical pathway to decrease and resolve pain and irritability of unknown origin (PIUO) in children with severe neurological impairments (SNI). Children with SNI are usually nonverbal, non-mobile, and have limited cognitive abilities. SNI is a result of various conditions which include severe cerebral palsy, traumatic brain injuries, childhood neurodegenerative diseases, and other genetic conditions. Examining a clinical pathway called the PIUO Pathway was the goal of our Phase I investigation into the underlying causes of pain and irritability in children with SNI.

METHODS

- Eligibility: children aged 6 months to 18 years with SNI and have PIUO.
- Waitlist-controlled RCT design with children randomized to the PIUO Pathway or Waitlist (standard care) treatment groups.
- The PIUO Pathway



History and Physical Exam



Screening Tests:

- 1. Urinalysis
- 2. Ultrasound abdominal
- 3. Gastric pH (if G-tube present)
- 4. Bloodwork



Pharmacology

DEMOGRAPHICS

72 participants enrolled.





Average age of participants is 6.5. The youngest participant at baseline is 7 months old and the oldest is 18 years old.

SUCCESSFUL! ~30% of

Pain is Resolved or Identified

Currently, Participants Who Completed Phase I:



19.4%

Pain Resolved



9.7% **Pain Identified**

The PIUO Pathway may streamline pain management for this population and

improve the well-being of children and their families.



RESULTS



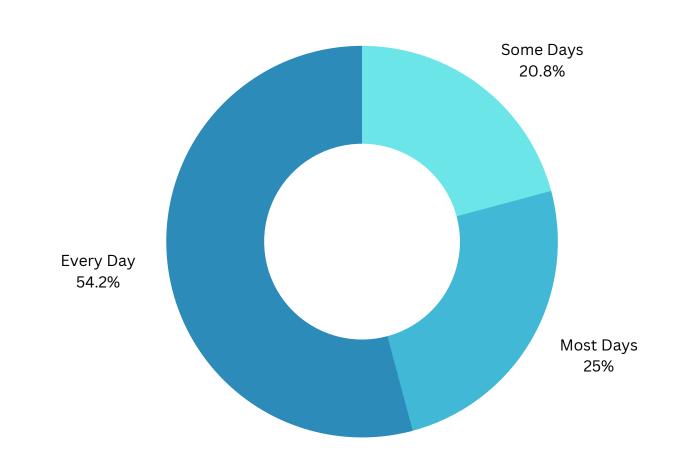




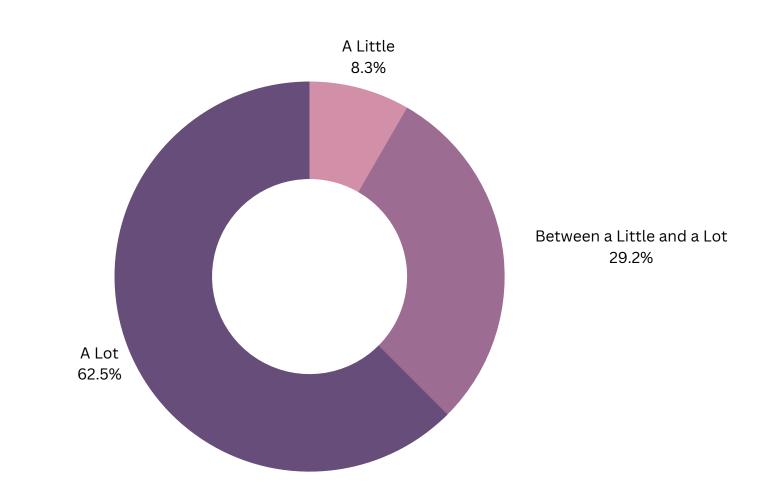


Parent-reported Timing and Distress for Participants Experiencing Pain and Irritability at Baseline

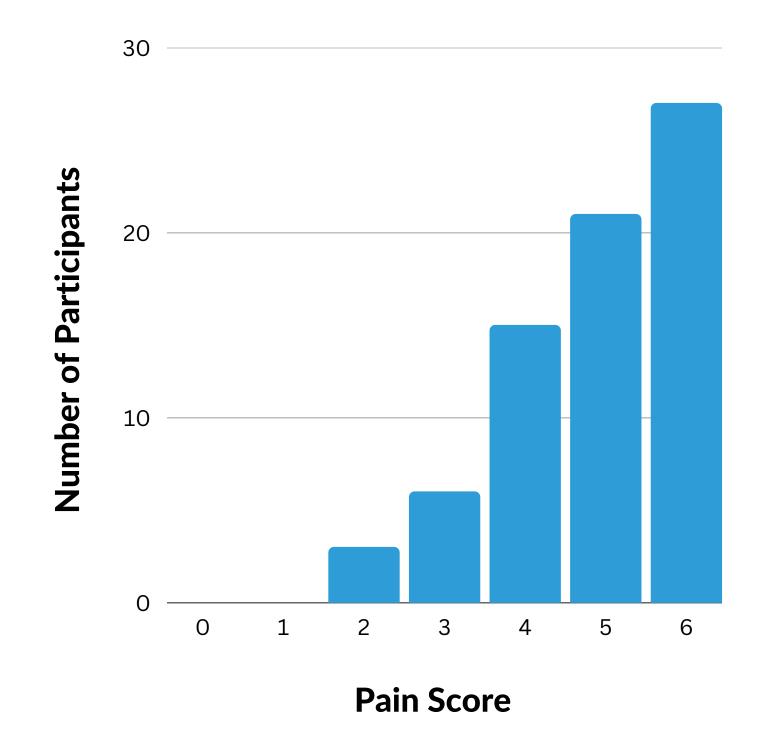
How often has your child experienced pain and irritability in the last two weeks?



Thinking about the last time your child had pain and irritability, how much did they have?



Total average baseline pain score is 4.9 out of 6 (maximum score).



REFERENCE

Siden H et al. Optimizing the Management of Pain and Irritability in Children with Severe Neurological Impairments. ClinicalTrials.gov; 2019:1-20.



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