

# Promoting Participation in Large, Multi-site Clinical Trials of Neurocognitive Functioning: Use of a Brief, Computerized Neurocognitive Battery with Pediatric Patients with Cancer

CHILDREN'S  
ONCOLOGY  
GROUP

The world's childhood cancer experts

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## Background

- Survivors of acute lymphoblastic leukemia (ALL) are at risk for neurocognitive deficits, but little is known about the magnitude of the deficits or the time course of their evolution in pediatric patients.
- The majority of research in this area has been typified by small-sample, cross-sectional studies using a variety of neurocognitive assessment tools.
- Computerized assessment batteries have advantages over conventional paper-pencil tasks, including cost, ease of administration, and suitability for longitudinal evaluations over shorter intervals of time.
- To address gaps in our knowledge while increasing participation and compliance, we selected a brief computerized battery (CogState) to prospectively examine neurocognitive functioning in children and teens with high-risk ALL in the context of a Children's Oncology Group (COG) clinical trial.

## Objective

- To evaluate our progress on project feasibility benchmarks, including:
  - Site participation of at least 100 COG institutions.
  - Participant recruitment of at least 55% of age-eligible patients.
  - Data collection rate of at least 90% of enrolled, on-study participants at each time point.

## Methods

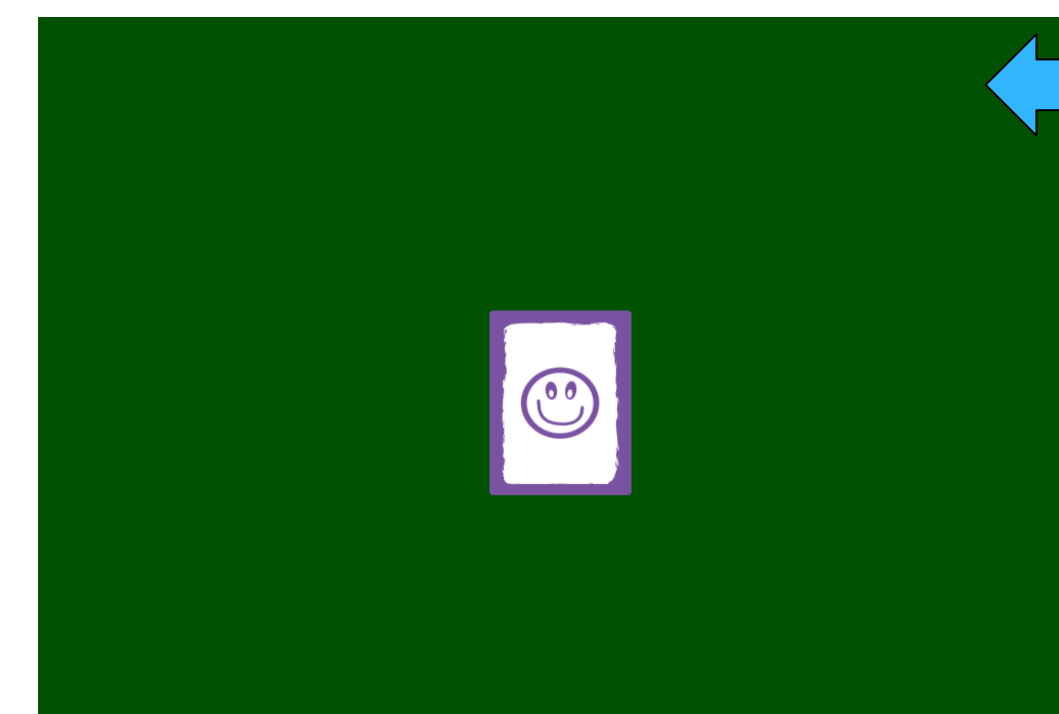
### Procedures

- Participants are English or Spanish-speaking children aged 6-11 years old (mean age = 9.4, 53% male) enrolled on a COG phase III high-risk ALL trial.
- Males complete testing at 6 timepoints, and females complete testing at 5 timepoints, as follows:
  - Consolidation – approximately 3 months from diagnosis
  - Maintenance 2 – approximately 13 months from diagnosis
  - Maintenance 4 – approximately 19 months from diagnosis
  - Maintenance 6 – approximately 25 months from diagnosis
  - Maintenance 10 (males only) – approximately 37 months from diagnosis
  - 1 year post-treatment – approximately 37 months (females) or 49 months from diagnosis (males)

### Measures

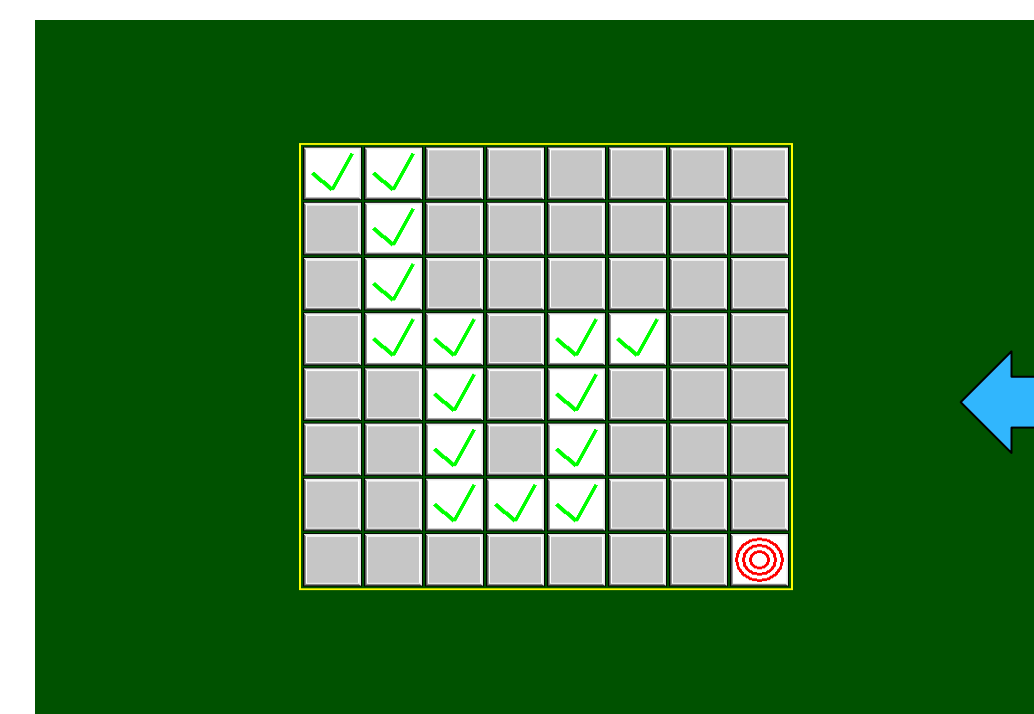
- CogState** – A 25-minute computerized assessment of processing speed, attention, working memory, memory, and executive function. Five tasks were used in the current study, including:
  - Detection*: psychomotor function
  - Identification*: sustained attention
  - One-card Learning*: learning and memory
  - One-back*: working memory
  - Groton Maze-Learning Task*: visual learning and executive functioning
- Behavior Rating Inventory of Executive Function (BRIEF)** – A parent-completed rating scale of executive function. The *Working Memory* subscale and *Behavioral Regulation* and *Metacognition Indices* were used for this study.

## CogState Tasks



### Card-based tasks:

- Detection**: Press the “yes” button every time a card flips over.
- Identification**: Press the “yes” button if the card is red and the “no” button if it is black.
- One Card Learning**: If the card has appeared before, press the “yes” button; if it has not, press the “no” button.
- One-Back**: If the card is the same as the one immediately before it, press the “yes” button; if it is not, press the “no” button.



### Groton Maze Learning Task (GMLT):

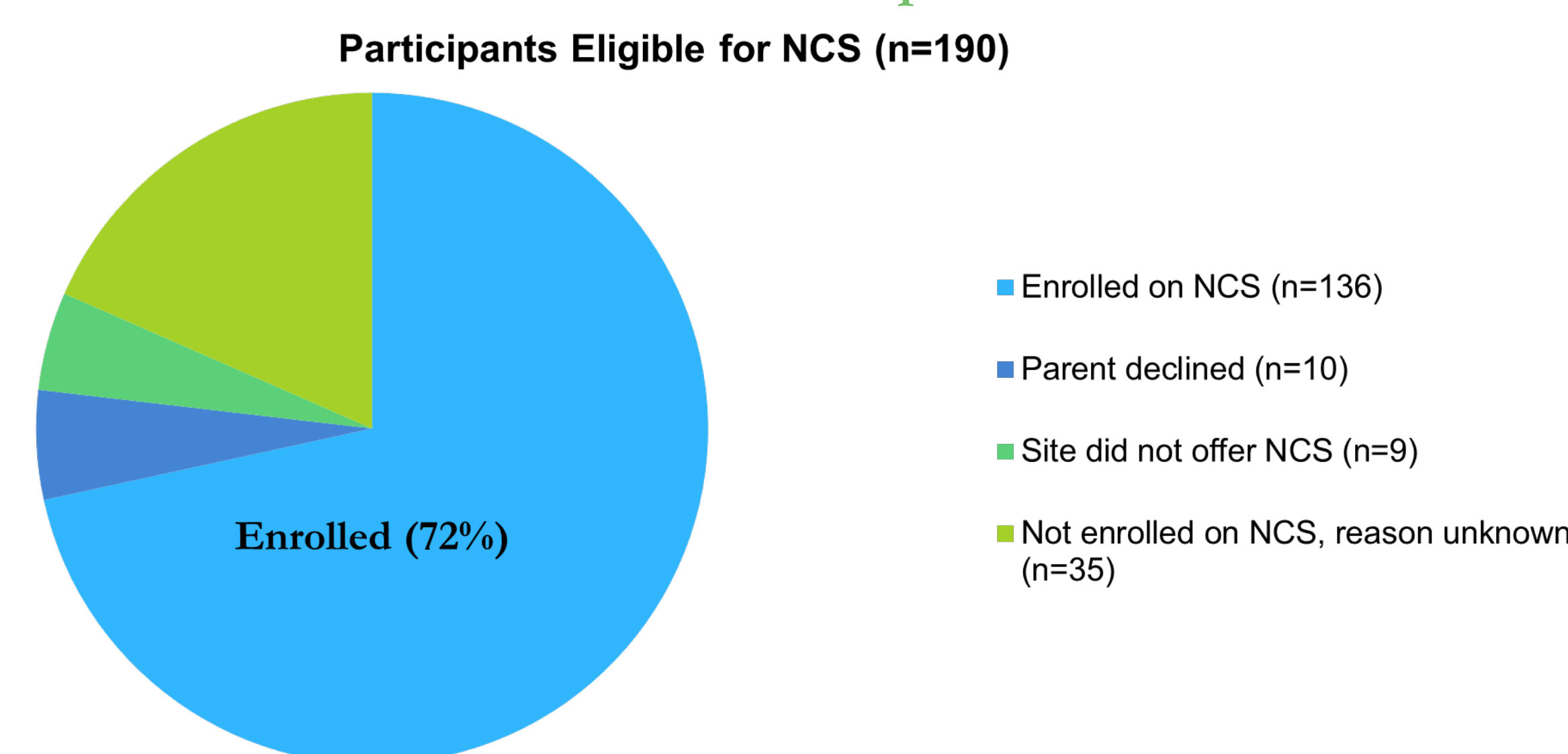
- Find the same pathway through the maze over repeated trials.

## Results

### Site Participation

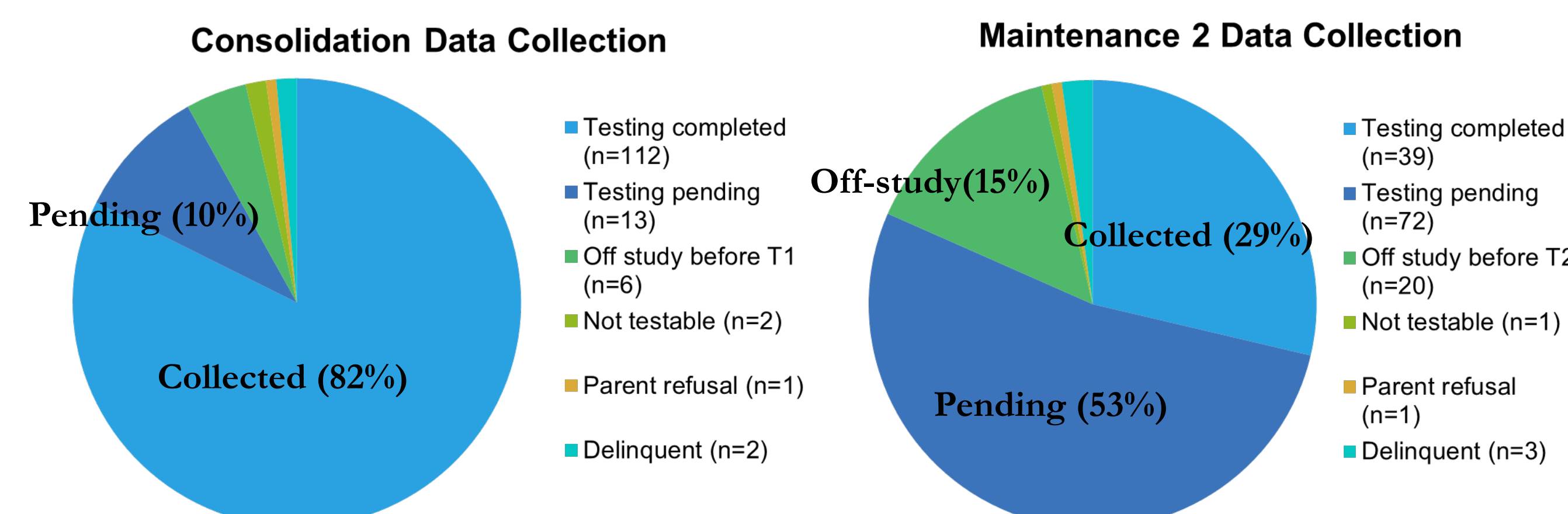
- 120 out of 189 COG sites (63.5%) that have opened the ALL treatment study are participating in the Neurocognitive Study (NCS).
- 329 users, mainly nurses and CRAs, have accessed the CogState program
- 125 users have completed online training to administer the testing.

### Patient Participation



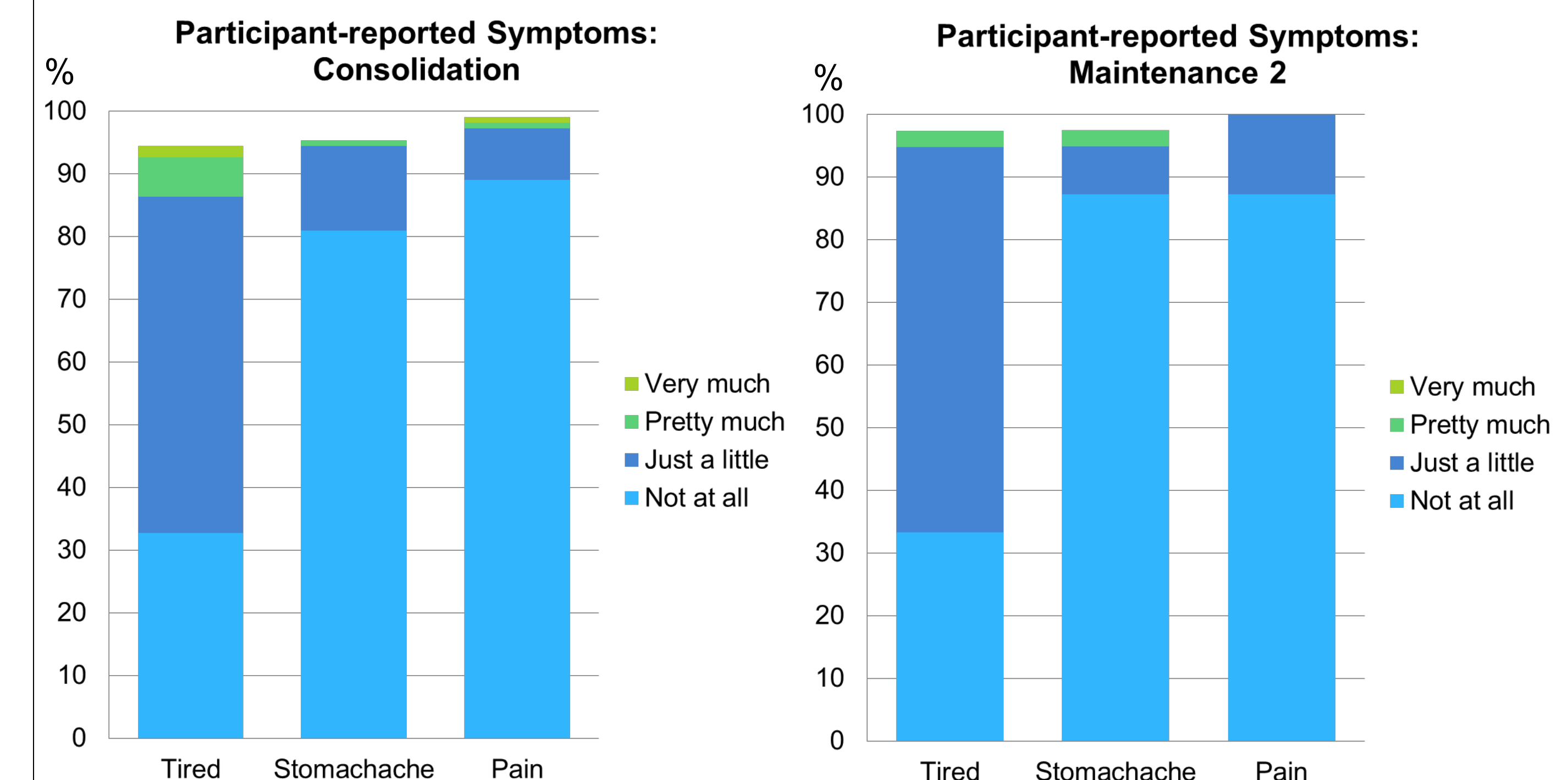
### Data Collection

- 95.7% of T1 data and 93.2% of T2 data have been submitted for participants who remain on study and have passed the testing window.



## Data Integrity

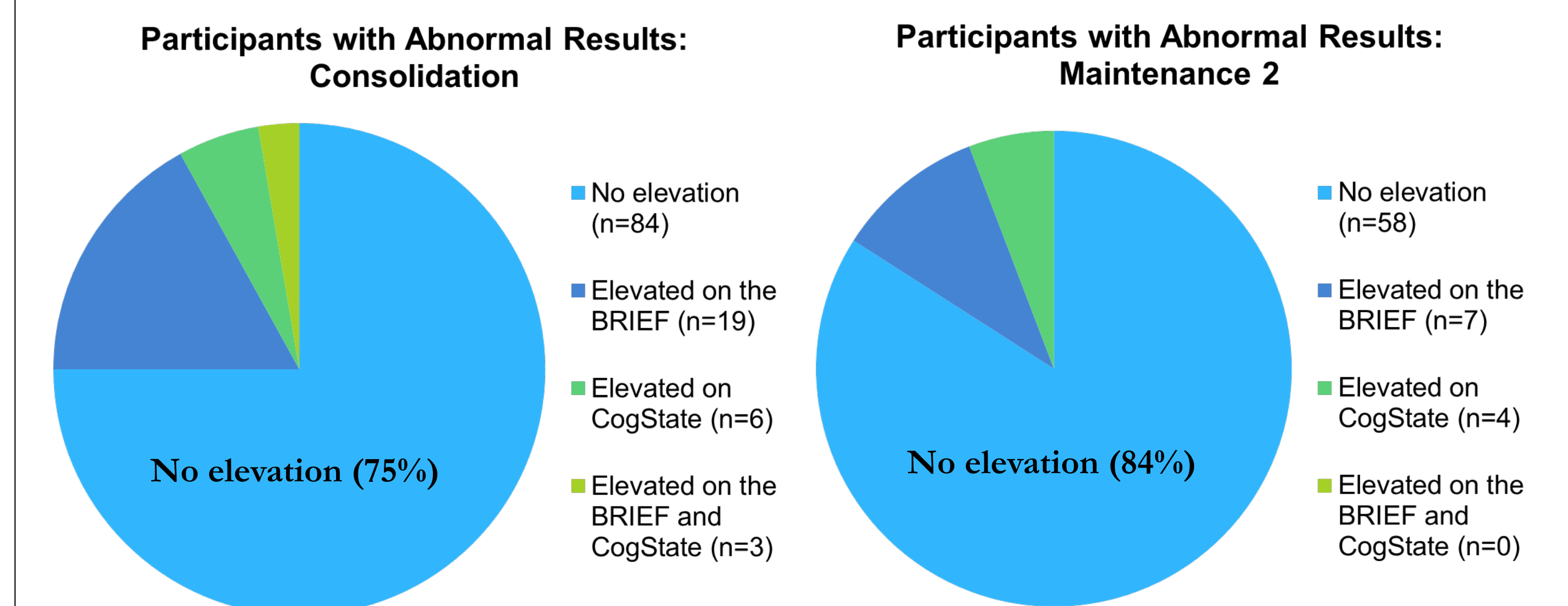
- Participants were asked about somatic complaints immediately prior to completing CogState at each timepoint.



- Data completion and integrity checks, designed to detect poor effort or misunderstanding of the tasks, indicated that >95% of participants completed the battery and the majority of participants (>86%) provided valid data.

## Data Description

- Ratings are considered elevated when they are 1.5 SD above (BRIEF) or below (CogState) the mean of the standardization sample. Feedback on elevated performance is communicated to the child's physician via letter.



## Summary and Conclusions

- Based on these preliminary data, CogState appears to be a feasible method to conduct research assessments in large, multi-center trials.
- Using a brief, computerized battery may have advantages over traditional neurocognitive tests when evaluating outcomes at the cooperative group level, including test administration at sites without psychologists, brevity, test administration in a clinic setting, low cost, and reduced practice effects.
- Further research is required to determine the sensitivity and specificity of computerized tools like CogState to changes in neurocognitive functioning that may occur following treatment for high-risk ALL.