**Title**: Decisional Capacity and Cognitive Outcome Measures in Youth and Adults with Down Syndrome

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**Introduction**: In clinical trials for people with Intellectual and Developmental Disabilities (IDD), it is important to make sure that researchers pay close attention to ethical considerations, especially for studies with potential risk. One aspect that has rarely been studied in this population is decisional capacity and how much information people with Down Syndrome (DS) understand when providing assent to join a study. Some researchers have analyzed general feelings and attitudes towards those with IDD participating in clinical trials, both from the parents’ perspective and from the individuals themselves (Horner‐Johnson & Bailey, 2013, Reines et al. 2017). However, there have been few, if any, studies examining people with DS and how well they understand the aspects of participating in a clinical trial. The current study aims to measure how children and adults with DS understand and make decisions about being a part of research, using a similar design to a study of decisional capacity for informed consent in FXS (Wheeler et al. 2020). Our primary aim is to see what aspects of health, cognition, and memory might predict better scores on our assessment of decisional capacity, including verbal fluency, IQ, and parent-reported Obstructive Sleep Apnea (OSA). We hypothesize that higher verbal fluency, verbal IQ, and executive function would predict higher scores on our measure of decisional capacity.

**Method**: We administered cognitive testing with children and adults with DS using the MacCAT-CR (Appelbaum, P. S., & Grisso, T. (2001)), the KBIT-2 to collect verbal and nonverbal IQ scores, and tasks from the Arizona Memory Assessment for Preschoolers and Special Populations (A-MAP) that measure executive control, short term memory, and verbal fluency. For the MacCAT-CR, participants were given a brief presentation on a tablet about a real-world clinical trial of a new OSA treatment for people with DS. Participants were informed that they would not be taking part in the drug trial but were only going to be asked questions about their thoughts about it. The MacCAT-CR assesses abilities across the core domains of decision making capacity including understanding information presented, appreciating the potential impact of study participation on a participant, reasoning to make a decision and stating a consistent decision.

**Results**: 43 participants with DS (56% male) from ages 7-34 years (Mage = 19.49 years) enrolled in the study. A total of 40 participants were able to complete every measure while 3 participants struggled to complete at least one of our measures, due to low verbal ability or lack of understanding. We ran a simple linear regression analysis to see how well Verbal Fluency, List Learning, Executive Control, KBIT Verbal and Nonverbal raw scores, and parent-reported OSA predicted MacCAT-CR scores. We found a significant regression (F(6,33) = 14.301, p<.001, R2 = .722) with our model explaining approximately 72% of the variance in MacCAT-CR scores (Mscore = 26.28, SD = 19.35, range = 2-76). MacCAT-CR score was also significantly correlated with two measures in particular: A-MAP List Learning score (t = 3.965, p<.001) and KBIT Verbal Raw score (t = 3.487, p = .001), suggesting that decisional capacity scores were primarily driven by child’s verbal memory ability and verbal IQ.

**Discussion:** To our knowledge, this is the first study to quantitatively measure decisional capacity in people with DS, which is important to consider as more research is being conducted with this population over time. Our results suggest that those who had a better grasp of the study concepts and communicating their thoughts ultimately were those with higher verbal ability and verbal memory overall, whereas we did not see any relationship with the MacCAT-CR score and age, gender, parent-reported OSA, or verbal fluency. This result is likely because the MacCAT-CR involves open-ended questions that might be too abstract for some, and individuals with higher verbal IQ had an easier time expressing their answers and their thought process. This research highlights the importance of making consenting materials as clear as possible for those with IDD, as well as including visual aids like a picture presentation to ensure those who are less verbal are given that extra assistance to ensure a meaningful consent/assent process and reduce barriers to participate in clinical trials.

**References:**

* Horner‐Johnson, W., & Bailey, D. (2013). Assessing understanding and obtaining consent from adults with intellectual disabilities for a health promotion study. *Journal of policy and practice in intellectual disabilities*, *10*(3), 260-265.
* Reines, V., Charen, K., Rosser, T., Eisen, A., Sherman, S. L., & Visootsak, J. (2017). Parental perspectives on pharmacological clinical trials: a qualitative study in Down syndrome and fragile X syndrome. *Journal of Genetic Counseling*, *26*, 1333-1340.
* Wheeler, A. C., Wylie, A., Raspa, M., Villagomez, A., Miller, K., Edwards, A., ... & Bailey, D. B. (2020). Decisional capacity for informed consent in males and females with fragile X syndrome. *Journal of autism and developmental disorders*, *50*, 1725-1747.
* Appelbaum, P. S., & Grisso, T. (2001). *MacArthur competence assessment tool for clinical research (MacCAT-CR)*. professional resource press/professional resource exchange.