

## The Impact of Oral Nutritional Supplement Plus Dietary Counseling on Growth Outcomes in Young Children

## Featuring:

Dr. John Stutts, MD, MPH, FAAP
Pediatric Gastroenterologist
Pediatric Medical Director
Abbott Nutrition

Dr. Grace Niemiro, PhD
Research Scientist
Abbott Nutrition
University of Illinois Urbana-Champaign,
Champaign County, Illinois, United States

## **TRANSCRIPT**

**Narrator:** Welcome to the Clinical Nutrition Conversations Videocast brought to you by the Abbott Nutrition Health Institute. In today's episode, we are joined by Dr. John Stutts and Dr. Grace Niemiro, lead scientist of a recent multi-site, randomized controlled trial, investigating the impact of an oral nutrition supplement plus dietary counseling on growth outcomes in young children.

Dr. Niemiro is a research scientist at Abbott Nutrition. She earned her PhD in kinesiology and community health from the University of Illinois at Urbana-Champaign. Joining the conversation is our moderator, Dr. John Stutts a pediatric gastroenterologist.

Dr. Stutts also serves as the Pediatric Medical Director at Abbott Nutrition. Together, they will explore the study's design, key findings, and implications for clinical practice in addressing pediatric undernutrition.

**John Stutts:** Well, it's great to be with you today, Dr. Niemiro. So, to begin, could you share a bit about your background and what led you to focus your research on pediatric nutrition and growth?

**Grace Niemiro:** Thanks so much, Dr. Stutts. It's great to be here and thank you so much for having me.



I actually started my research journey in pediatrics and that was during my PhD program. I evaluated the impact of obesity on children's immune systems and during that time, I conducted clinical research studies with children and adults during my academic career. And I've continued to work in preclinical and clinical research at Abbott.

And throughout this whole time, I really became inspired to further look into how nutrition and exercise may affect how children grow, because it is so important for their continued development beyond childhood.

**John Stutts:** Thanks for that introduction for everyone. So, your recent study involved a large, 17-site trial of an oral nutrition supplement plus dietary counseling in U.S. children. What was the motivation behind designing such a comprehensive intervention?

**Grace Niemiro:** So, when designing a clinical trial, it's important to ensure that the trial includes a representative sample of a population. So, for this particular study, we wanted to make sure that an overall sample of children in the U.S. who meet the criteria for mild to moderate undernutrition were represented. Therefore, we decided to recruit children from various locations within the United States.

**John Stutts:** Okay, so before your study, what was the prevailing understanding of how oral nutrition supplements impact growth in undernourished children?

**Grace Niemiro:** Undernourished children may have different reasons as to why they are not meeting their growth norms, and many times it is due to not taking in enough calories. Research has also shown that undernutrition in a child, even if for a short time, can have long lasting impacts on their health.

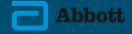
The American Academy of Pediatrics, or AAP, emphasizes to first promote the increase of calories and nutrients using a whole foods approach, what we will refer to as dietary counseling. Oral nutritional supplements can be a tool to help children increase their caloric intake when they are behind in growth.

John Stutts: Okay, so that being said, can you walk us through how you structured the study?

**Grace Niemiro:** Absolutely. We used a randomized controlled trial design to assess the impact of oral nutritional supplements, plus dietary counseling, compared to dietary counseling alone in undernourished children over 120 days in the United States. We enrolled 279 children who were 3 to 8 years old and had at least one indicator of undernutrition at a single point in time. Participants were randomized to either the Oral Nutritional Supplement Group plus dietary counseling or Dietary Counseling Alone.

John Stutts: Okay, so what were some of the most significant findings from this clinical trial?







**Grace Niemiro:** Well, Dr. Stutts, this was a very large trial, and I'd be happy to share some of the really exciting results that we saw. Our primary outcome, which was the Change in Weight-for-Age Z-Score at 120 days, was significantly higher in our Oral Nutritional Supplement Plus Dietary Counseling group compared to Dietary Counseling Alone.

We also found a significantly higher change in various weight measurements at 30, 60, and 120 days, such as Weight-for-Age Percentile, Weight-for-Age Z-Score, and overall weight in the Oral Nutritional Supplement Plus Dietary Counseling group compared to Dietary Counseling Alone.

For height-related growth measures, we found that there were significantly higher changes in Height-for-Age Percentile, and overall height over the 120-day period in the Oral Nutritional Supplement Plus Dietary Counseling group compared to Dietary Counseling Alone.

**John Stutts:** Okay, so your findings show dietary counseling plus an oral nutrition supplement resulted in proportional growth. Can you tell us a bit more about this outcome and why it's important?

**Grace Niemiro:** Yes. Understanding growth as it relates to more than just height and weight is important, especially considering in the United States there is an overweight and obesity epidemic.

We found a significantly higher change in proportional growth measures, like BMI-for-Age Percentiles and Z-Scores, and Weight-for-Height Percentiles and Z-Scores in the Oral Nutritional Supplement Plus Dietary Counseling group compared to Dietary Counseling Alone. The BMI-for-Age Percentiles of children and both groups did not approach the level that is indicative of overweight or obese status in children over the whole course of the trial.

**John Stutts:** So, your findings also showed muscle gain without excess fat gain. Can you tell us a bit more about that outcome and why it might be important to practicing clinicians?

**Grace Niemiro:** While proportional growth measurements are very important. We also wanted to assess body composition in the children in our study. We used a method that measures the circumference around the upper arm and combination of skin fold thickness to calculate muscle and fat approximations of the upper arm. In this study, we found that children in the Oral Nutritional Supplement Plus Dietary Counseling group had a significantly higher change in arm muscle area compared to the Dietary Counseling Alone group.

We also found no differences between the groups in arm fat area or arm fat indexes.

**John Stutts:** Okay, so Dr. Niemiro, were there any results that surprised you or really challenged your expectations?







**Grace Niemiro:** Yes, I'd be happy to share those with you. Two outcomes that we were very surprised by, were that we found no differences in our assessment of dietary diversity and appetite levels between the groups over the 120-day period. We had asked parents or legal guardians to complete a 24-hour dietary recall and appetite score of their children at baseline, 30, 60 and 120 days.

At each time point, we did not find differences between the groups and the intake of diverse food groups or appetite levels. I was really excited to find this result because the goal of dietary counseling is to support food intake to help reverse undernutrition as a first approach. Sometimes children need a little extra help from oral nutritional supplements, and our study shows that there doesn't seem to be a replacement of food groups or appetite with the use of oral nutritional supplements.

**John Stutts:** So, the study also tracked caregiver perceptions and stress levels. What insights did you gain from these subjective measures and how might they influence future interventions?

**Grace Niemiro:** We asked parents or legal guardians a variety of questions related to their stress levels and their perception of their child's growth throughout the study period. We found no differences and stress levels between groups at any time point over the 120-day period. However, we found that there was a significantly higher percentage of parents and legal guardians who were satisfied with their child's growth and who would recommend the intervention their child received in the Oral Nutritional Supplement Group Plus Dietary Counseling compared to the Dietary Counseling group alone.

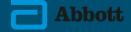
As you mentioned, these are subjective measures, but they are really exciting for us to see. I'd be curious to see if future trials can research what specifically about the intervention helped them to feel satisfied with their child's growth and use that to explore our product innovation.

**John Stutts:** That would be great to see. So, I am interested in how this work adds to the growing body of literature on the use of oral nutrition supplementation in the undernourished pediatric population.

**Grace Niemiro:** Absolutely, and this is a great point. There are many studies across the world that look at the impact of dietary counseling and/or oral nutritional supplements in undernourished children. It's a worldwide concern, and that's especially true in low-income countries. But there are relatively less trials conducted in high income countries such as the United States and there's a perception that children in the U.S. do not suffer from undernutrition.

But recent studies have found that 1 in 8 children exhibit at least one indicator of pediatric undernutrition within the U.S. And to our knowledge, this trial is one of the first studies of oral nutritional supplement plus dietary counseling compared to dietary counseling alone in undernourished children in the United States. We







are excited that other studies have also shown the positive impact of oral nutritional supplements on pediatric undernutrition in other countries.

**John Stutts:** You know, as a clinician, I believe your findings, alongside the growing body of literature on the use of oral nutritional supplements in managing pediatric nutrition, can support clinicians with an evidence-based approach and a valuable addition to the health care provider toolbox in helping manage these children. So where can our audience learn more about this study?

**Grace Niemiro:** I'm very excited to share that I presented some of the growth measures that I shared here today in an abstract through the American Society for Nutrition. This is a really new study, and we plan to submit this to a peer-reviewed scientific journal, so please stay tuned on where you can read the full report.

John Stutts: Okay, so looking ahead, what additional research would you like to see to build on your findings?

**Grace Niemiro:** Well, Dr. Stutts, while this study was very comprehensive, I would like to see the research expanded in future trials by examining other measures of body composition that can also measure bone density. I would also like to examine caloric intake and how might longer term consumption of oral nutritional supplements might impact these same measures.

**John Stutts:** All right. Well, Dr. Niemiro, thank you, genuinely, for sharing your insights and the impactful findings from your recent study. Your work continues to advance our understanding of pediatric nutrition and growth, and it really offers valuable guidance for not only clinicians and caregivers, but also researchers, and we appreciate your dedication to improving child health outcomes and we look forward to seeing how your research continues to shape the field.



