

Parent Council FAQ for the website

What if my child is uncooperative?

The assessors and therapists are well-trained to try different ways to encourage and engage your child and turn the behavior around. During the first 3 years of life, almost all children show what adults label as “uncooperative” behavior – often many times per day. Around 18 months of age, a strong sense of self appears – and children are expressing their likes and dislikes all the time. During the high-intensity I-ACQUIRE therapy sessions, the therapist is asking the child to try new and often very difficult ways of using their arms, hands, and fingers. The child’s frustration, lack of cooperation, defiance, and simple boredom are things that occur “typically” during a course of high-intensity therapy. Fortunately, there are usually just as many positive and fun times! Also, we have seen a child be uncooperative for a period, and then turn around and experience real progress or success.

What do I do if I have a conflict with the therapist?

It is really important to try to talk with the therapist about differences you may have. Therapy in the home, and with you as a parent around, may allow you to see things or gain new ideas that could be helpful to resolve the conflict.

If your conflict cannot be easily resolved, please contact the Principal Investigator at your site who is named on your copy of the parent permission/informed consent document.

Can my child still receive the constraint-induced movement therapy (CIMT) at a later time if my child is in the control group?

Yes, every child in the “usual and customary” (or control) group is eligible to receive the CIMT – at no cost – after the 6-month follow-up assessment is completed. This is discussed in advance with all parents.

When should I start to see results from treatment for my child?

As scientists, we designed this study because we do not have answers yet to this question. We truly hope your child will benefit from participation in this study, but understanding if and how soon benefits of this intervention will appear is why we are conducting the study on very young children who have had perinatal stroke.

What happens if my child gets sick? Will the sessions be made up?

Children can miss up to 3 days of therapy due to sickness. If it can be worked out, the therapist can schedule with you for make-up sessions if this meets with your schedule and the therapist’s availability.

Can I have a copy of the assessment results?

The results of the assessments we conduct can be shared with you when the entire I-ACQUIRE Trial is completed. This is standard practice for Phase 3 clinical trials. However, since parents often observe their child during at least some of the assessment, you will see which skills your child is showing and may notice others that have room for improvement. Your child's therapist is the very best source of ideas to help you and your child make gains or improvements.

Can I have a copy of the assessment results sent to my child's physician or therapist?

The way in which we give the assessments adheres to a specific research protocol and is not designed to substitute for individual clinical assessments to guide treatment recommendations for an individual child. Our research study does not provide the detailed written assessment reports that skilled assessors or testers typically prepare for clinical evaluations.

Can I see the results of the study? When?

As soon as the study results have been accepted for publication in a peer-review journal, then you and others can see the results. [ND7]

Will any of my travel be reimbursed?

Currently, all families receive a standard amount of \$75.00 for each assessment visit, based on an average of local driving and other study-related expenses (an extra meal, parking, etc.) We do not cover any travel expenses for families who choose to come from out-of-town. Out-of-town families must agree in advance to adhere to all of the assessments and visits at their own expense.

Are there housing options available for families traveling from out of town?

Yes, there are different options available in the communities around each site. Your site may be able to provide additional information. Also, if you are coming from out-of-town, remember you will need accommodations for follow-up visits and assessments.

How do I know if my baby will tolerate 6 hours of therapy each day?

It is our experience that children do very well with 6 hours of therapy each day. The majority of I-ACQUIRE is play-like. Crying and fussing may sometimes occur, and we consider this natural. We will work closely with your family to have this be a positive experience.

My child is currently doing some CIMT. Is she/he still eligible to participate in the study?

If your child has received or is scheduled to receive at least 10 days of CIMT that lasts 2 hours (or more) per session, then your child is not eligible for this study.

Will the cast be worn 24 hours a day when my child receives I-ACQUIRE?

Yes, your child will wear the cast continuously until the last 3 days of therapy. The therapist will remove the cast once a week for a brief period to check the skin, to wash your child's arm, and also to allow your child to do some movements with that entire arm.

Will my child lose function of the casted arm?

Previous research has shown no loss of function. By the way, thousands of children wear casts for this long due to a broken bone or surgery and research shows there have been no long-term negative effects.

What time of day will the therapy start?

Every family and therapist set up a schedule that works best for the child and for them. Day to day variation can occur, although most families like to have a regular time. For young children, starting in the morning is an ideal time when they are naturally active and curious.

Am I allowed to get involved in the I-ACQUIRE therapy?

Yes! Parents are actively involved in many ways. This involves observing and sometimes participating in the therapy sessions. In addition to the therapist-led sessions each day, parents receive support for an additional home program that lasts for about 45 minutes per day and is designed to strengthen and enhance the new skills your child is learning during the formal therapy sessions. Your child's therapist will teach you and involve you in this. Also, you and the therapist will discuss goals for your child and work together for a post-treatment "Transfer Package" that you can carry out after the 4 weeks of I-ACQUIRE.

What does I-ACQUIRE stand for?

The acronym "I-ACQUIRE" has a long story. Originally, in the late 1990s, some of our team members developed this novel form of Constraint-Induced Movement Therapy, and then created a trademark name – ACQUIRE – after it proved to result in large and lasting benefits for children age 3 and older. We added "I" to indicate that we are using ACQUIRE with Infants. The letters in ACQUIRE mean:

Acquisition of new motor skills through

Continuous practice and shaping to produce

Quality movement of the

Upper extremity through

Intensive therapy and

Reinforcement in

Everyday patterns and places

Why do I have to return to the actual site for a follow-up visit? Why should I return?^[ND8]

It is critical for the success of this study that families adhere to the assessment schedule and attend all assessments. Without data from both assessments after treatment, we cannot know whether the I-ACQUIRE intervention is effective.

An NIH Phase 3 Clinical Trial is a major endeavor, investing large amounts of resources – financial, clinical, and practical – in conducting a study to answer an important question about whether a treatment works well. The parent permission agreement contains a section that lists parent responsibilities. One of the most important is bringing the child in for every assessment. If there is a reason that you feel it is a burden or that you are not likely to return for assessments, then it is unfair to others – and to the field of pediatric rehabilitation and stroke recovery – to sign up for this trial. The study of this treatment (provided at no cost) will be useless to advance scientific and clinical knowledge if families do not participate in all follow-up sessions.

What happened to the study with COVID-19?

All of our clinical sites had to “pause” due to the safety and health risks at the start of the Coronavirus Pandemic. Over the next several months, we developed plans at the local levels and had our Institutional Review Boards – locally and centrally – review these plans. Starting in July (after 3 ½ months of being in “trial suspension”) some of our sites were able to open up. We actively monitor the situation, and each family can choose whether to wait – or proceed – based on knowledge of their local risk and their own family’s risk factors.

When will the study start up again?

The study has started again – and by the end of August, 7 of our sites were approved to continue with recruiting, assessing, and treating children. We hope even more sites will be safe enough to open up in the coming months. There is much to be learned – and taking full safety measures for the study is of highest importance to everyone on the I-ACQUIRE Project study team.