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Study Number (IRB00111766)

Frontline Home-based Behavioral Treatment for Tics

Research Study at the Johns Hopkins Hospital **PI: Harvey S. Singer MD**

There is no cure for tics and a variety of behavioral and pharmacotherapies have been used successfully to suppress tics. Comprehensive Behavioral Intervention for Tics (CBIT) is a safe, effective, front-line treatment for Tourette syndrome (TS). Unfortunately, there is an acute shortage of appropriately trained clinicians available to assist affected individuals.

DVD: In cooperation with the Digital Media Center at the Johns Hopkins Hospital (JHH), we have produced an educational CBIT-based DVD and instructional guide, for parent use in the home environment. This DVD contains a brief overview of Tourette syndrome, specific information on the classification of tics, the rationale for habit reversal training (HRT), and specific instructions regarding awareness, competing response, and reinforcement training.

Goals: This research is being done to determine whether our home-based behavioral therapy can be successfully used to treat tics in children with TS. In this study, our goal is to determine whether our instructional video can provide parents of children with TS with the tools necessary to successfully use behavioral therapy at home. We also want to determine the effectiveness of home-based behavioral therapy as compared to improvement achieved when the therapy is provided by a trained therapist.

Subjects: Children with Tourette syndrome (TS) or a chronic motor/vocal tic disorder (CTD), ages 7-13 years, with observable tics of at least moderate severity.

Screening: To determine whether your child can be in the study, you will be asked to complete several study questionnaires to assess your child's medical history, developmental milestones, history of tics, prior therapies, severity of tics, and screens for attention deficit hyperactivity disorder and obsessive compulsive disorder.

Baseline evaluation: Qualified participants will be scheduled for a formal in-person Baseline evaluation at Johns Hopkins Hospital. This evaluation will include a history, physical examination, completion of rating scales, and a family background questionnaire.

Treatment groups: After the baseline evaluation, eligible children will be randomly assigned ("like flipping a coin") by computer into either a Home-based DVD or a trained therapist-directed treatment group. This is a 10 week study.

a) **Home-based DVD:** The DVD and training materials will be mailed to your home.

b) **Trained therapist-directed behavior group:** Face-face training will be administered at Johns Hopkins over a 10 week period; 6 weekly sessions (1-6) and sessions at 8 and 10 weeks. Each session will be approximately one-hour.

Final assessment: A final assessment for both treatment groups, after the 10 weeks of treatment, will be held at the Johns Hopkins Hospital.

Potential benefits: A possible direct benefit for your child from being in this study is the reduction in his/her tics. If your child takes part in this study, your child may help others in the future.

Costs: No cost. A small monetary payment (\$35) will be provided to cover expenses associated with the baseline and 10 week evaluations. Parking passes will be provided for all study visits to JHH.

Contact information:

If you are interested in having your child participate or in learning more about this study, please send an e-mail to: ferenc@kennedykrieger.org or call (443) 923-4469